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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN, JR.

Legislation and Regulation Committee

Shirley Wheat, Chair, Public Member
Ramón Castellblanch, Public Member
Deborah Veale, RPh
Tappan Zee, Public Member

LEGISLATION AND REGULATION COMMITTEE REPORT

PART I – LEGISLATION

1. Board Sponsored Legislation for 2012

ATTACHMENT 1

1575 (Senate Committee on Business, Professions and Economic Development, Price, Chair)

Last Amend: June 20, 2012
Location: Assembly Appropriations
Status: Passed out of ASM Business Professions and Consumer Protection (6/19)
Board Position: Support (est. 5/1/2012)

Each year the Senate Committee on Business, Professions and Economic Development sponsors omnibus measures.

SB 1575 contains two omnibus proposals sponsored by the board:

- Section 4209 of the Business and Professions Code would provide the board with the authority to accept intern hours earned in another state, as specified, and to specify requirements for certifications of intern hours earned for pharmacist applicants. This language was approved by the board in October 2011.

- Section 4300.1 of the Business and Professions Code would ensure the board can put discipline on record even if the license is cancelled. This language was approved by the board in January 2012.

The bills attached are formatted to show the most recent version of the bill compared to current law (i.e., "amends the law" version).

As introduced, SB 1575 contained a provision sponsored by the Respiratory Care Board to add Section 144.5 to the Business and Professions Code to authorize a board to request – and require a local or state agency to provide – certified records, such as arrests, convictions, and other documents required to complete an applicant or licensee investigation. Staff has been advised that the Respiratory Care Board will be amending out this provision to address concerns by the American Council of Engineering Companies.

The bill was introduced on March 12, 2012, containing multiple omnibus provisions for various boards, bureaus and entities and, on April 16, was amended to include the boards sponsored provisions. The most recent version of the bill removes provisions related to massage therapists and makes other changes not related to pharmacy. The bill recently passed out of Assembly Business, Professions and Consumer Protection (June 19) and has been referred to Assembly Appropriations. This bill in its entirety is available at http://www.leginfo.ca.gov. **Attachment 1** contains the board's provisions.

STAFF RECOMMENDATION: No change

2. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

ATTACHMENT 2

Regulation of Dangerous Drugs and Devices

a. AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products

Board Position: Oppose *(Ver. Jan. 17, 2012)*
Last Amend: January 17, 2012
Location: Senate Third Reading File *(6/21/12)*

Summary: AB 389 seeks to establish the Standards for Service for Providers of Blood Clotting Products for Home Use Act by imposing specified requirements on providers of blood clotting products for home use. The board has expressed its opposition to the bill, citing concerns regarding jurisdiction and challenges in enforcing some of the provisions. The January 17, 2012, version of the bill removed references to home nursing services. The board reaffirmed its position of Oppose at the January and May 2012 Board Meetings. There have been no changes since the board established its position.

STAFF RECOMMENDATION: No change

b. AB 1442 (Wieckowski) Common Carriers to Transport Pharmaceutical Waste

Last Amend: June 14, 2012
Location: July 2, 2012 – Hearing set for SEN Environmental Quality
Board Position: Oppose Unless Amended

Summary: AB 1442 amends the Medical Waste Management Act (under the jurisdiction of the CDPH) to define, for purposes of the act, "pharmaceutical waste" and "common carrier"; to provide for a pharmaceutical waste hauling exemption; to allow the use of common carriers to transport pharmaceutical waste for disposal, and to specify what information must be maintained regarding the disposal and transporting of pharmaceutical waste.

During the May 2012 board meeting, members discussed this measure and some of the concerns the bill posed in the current form. These concerns discussed the need for controls in the movement of the drugs that are picked up and shipped. After discussion the board established an Oppose Unless Amended position.

The bill in its current form incorporates many of the changes requested by staff. In light of the changes incorporated at the request of the board and the author's office commitment to working with the board, staff recommends that the board consider changing its position on this bill to a neutral position.

STAFF RECOMMENDATION: Change to a neutral position.

c. AB 2348 (Mitchell) Registered Nurses: Dispensing Oral Contraception in Clinics

Last Amend: June 20, 2012
Location: SEN Business, Professions & Economic Development
Status: June 25, 2012 – Hearing set

Summary: The Nursing Practice Act authorizes a registered nurse to dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a specified clinic. This bill would, in addition, authorize a registered nurse to dispense drugs or devices upon an order issued by a certified nurse- midwife, nurse practitioner, or physician assistant if the nurse is functioning within a specified clinic. The bill would also authorize a registered nurse to dispense hormonal contraceptives pursuant to specified standardized procedures, if the nurse is functioning within a specified clinic.

On May 1, 2012, the Board took a "Watch" position. Since that time, the bill has been amended to specify the standardized procedure / protocol under which a Registered Nurse may dispense self-administered hormonal contraceptives and also administer injections of hormonal contraceptives, and makes other changes specific to the Nursing Practice Act.

STAFF RECOMMENDATION: Continue to Watch

d. SB 419 (Simitian) Solid Waste: Home Generated Sharps

Introduced: February 16, 2011
Location: On the Assembly Inactive File
Status: According to the author's staff, the bill is considered "inactive" and Senator Simitian may move the bill
Board Position: None

There has been no change in this measure since the May 1, 2012, Board Meeting.

Summary: Existing law permits hospitals and other entities to accept for disposal home-generated sharps, as specified. Currently a pharmaceutical manufacturer that sells or distributes a medication in California that is self-injected, as specified, is required to submit to the Department of Resource Recovery and Recycling a plan that describes what actions, if any, the manufacturer supports for the safe management of sharps. This bill would require that the manufacturers provide their reports to DRRR electronically and also make them readily accessible on the manufacturers' websites. The measure is currently on the Inactive File. The board has not taken a position on this bill, and staff continues to monitor its activity.

e. SB 1301 (Hernandez) Prescription Drugs: 90-Day Supply

Last Amend: May 1, 2012
Location: June 26 – Set for Hearing in Assembly Health
Board Position: Support (as Amended 4/16/12)

This measure would specify conditions under which a pharmacist may dispense a 90-day supply of a dangerous drug, as specified, without first receiving authorization from the prescriber. The Board established a position of Support on May 1. Since that time, the bill was amended to specify that a pharmacist shall not dispense a greater supply of a dangerous drug in accordance with the section, if the prescriber indicates "dispense as written" or words of similar meaning.

STAFF RECOMMENDATION: No Change

f. SB 1329 (Simitian) Prescription Drugs: Collection and Distribution Program

Last Amend: May 14, 2012
Location: Assembly Health
Hearing: June 19
Position: Support if Amended (A-3/29/12)

Summary: Under current law a county may establish a repository and distribution program under which a pharmacy may distribute donated/surplus medications, as defined, to persons in need of financial assistance. Currently, skilled nursing facilities, manufacturers, or pharmacy wholesalers may donate medications to a program. Under these programs, donated drugs must be either (1) dispensed to an eligible patient, (2) destroyed as pharmaceutical waste, or (3) returned to a reverse distributor. With certain exceptions, those who donate medications to these programs are not subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program. SB 1329 would expand repository and drug distribution programs by also allowing a county health officer to establish a program, and would expand the pool of defined entities that can donate drugs to the program. SB 1329 would also allow donated drugs to be transferred from one program to another. The bill would require certain information to be reported to the county, and would allow the board to request this information. The bill specifies entities, including the Board of Pharmacy, that may prohibit a pharmacy or clinic from participating in a program, as specified.

At the May 1, 2012 Board Meeting, the board established a position of Support if Amended. Since that time, staff has worked with the author's office to address the board's concerns. The current version of the bill contains some amendments that address the board's concerns, but there are a few areas that remain outstanding. Staff is continuing to work with Senator Simitian to address the board's concerns.

STAFF RECOMMENDATION: Maintain the board's position "Support if Amended"

Sunset Review and Legislative Oversight

g. SB 1237 (Price) – Sunset Extension to 2017

Last Amend: June 15, 2012
Location: Assembly Business, Professions & Consumer Protection
Hearing: June 26, 2012
Position: Support (A-4/30/12)

Summary: In November 2011, the Board provided its "Sunset Review Report 2011" to the Senate Committee on Business, Professions and Economic Development, and also made the report available on the board's public website. The board last underwent sunset review in 2002. Board President Stan Weisser and Executive Officer Giny Herold appeared before the Senate Committee on Business, Professions and Economic Development in March 2012.

The most recent version of the bill contains changes related to the Medical Board of California, the Physical Therapy Practice Act and the Naturopathic Doctors Act – no provisions related to the Board have changed. A copy of SB 1237 as Amended on June 15 is provided in Attachment 2.

STAFF RECOMMENDATION: Maintain Board Support

Licensing and Pharmacy Operations

h. AB 377 (Solorio) Hospital Central Fill Pharmacies

Last Amend: April 14, 20**11**
Board Position: Support if Amended (Ver. A-4/14/11)
Location: Last Location was Senate Appropriations (6/14/11)

Summary: AB 377 provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. The bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified. The board has conveyed its concerns with the bill (to move the new centralized packaging provisions away from the definition of consolidated hospital license). The sponsor has agreed to make this amendment, and staff has been advised that the bill will be moving forward in 2012. The board's Executive Officer participated in a meeting with various stakeholders, and amendments to the bill are expected – basically, taking the bill back to a 2009 version that the board supported.

The committee noted that the measure has not changed since the board established its position in April 2011. The board's Executive Officer will provide an update to the committee on this measure.

i. AB 1588 (Atkins) Reservist Licensees: Fees and Continuing Education

Last Amend: March 5, 2012
Board Position: None
Location: July 2, 2012 – Hearing in Senate Business, Professions & Economic Development
Board Position: The board has not previously discussed this measure

Summary: AB 1588 would require a licensing board to waive renewal fees and continuing education for a member of the California National Guard or member of the U.S. Armed Forces while they are on active duty. These provisions are specific to reservists, and are very similar to existing law (B&PC 114) related to active duty military.

The author's office has shared amendments that will further specify the term of such a waiver, and state that the licensee is unable to perform duties within the scope of practice for the license during the term it is waived. A copy of the Author's Fact Sheet and the current version of the bill are attached.

STAFF RECOMMEDATION: Support

j. AB 1896 (Chesbro) Tribal Health Programs: Health Care Practitioners

Last Amend: March 27, 2012
Board Position: None
Location: Assembly 3rd Reading File (6/21/12)

Summary: This measure seeks to codify into state law existing federal law (the Patient Protection and Affordable Care Act). This bill would specify that a healthcare professional employed by a tribal health program is exempt from state licensure if that health professional holds a license from another state.

Recently, it was brought to staff's attention that under the Federal provisions of the Indian Health Care Improvement Act, non-Indian patients may be extended health care at all tribal facilities. According to the California Rural Indian Health Board, Tribal Health Programs (THPs) have the authority *and desire* to serve the non-Indian population. The CRIHB notes that other non-California licensed providers also serve California residents (University of California, Veterans Administration). The CRIHB states that in many rural parts of California, THPs are the only providers in these regions and they operate as part of an integrated rural health care delivery system. They state the purpose of AB 1896 is to assist in remedying the shortage of doctors, dentists, nurses, and other providers by conforming State law to Federal law.

The board did not take a position on AB 1896 at the May 1, 2012, Board Meeting, but the committee may wish to discuss whether or not the board should take a position in light of the information provided to staff.

STAFF RECOMMENDATION: OPPOSE

k. AB 1904 (Block) Military Spouses: Expedited Licensure

Last Amend: June 12, 2012
Board Position: Support (I-2/22/12)
Location: July 2, 2012 – Hearing in Senate Business, Professions & Economic Development

Summary: As amended, this measure authorizes a board to expedite the licensure of an applicant that is a military spouse, and authorizes the board to adopt regulations to administer the provisions. Staff anticipates that this may impact two primary license types: Pharmacist, and Pharmacy Technician.

The former version of the bill provided for *temporary* licensure of applicants, as specified, and would have required the board to expedite the processing for the purpose of issuing the temporary license, specified the term of a temporary license, and authorized the board to promulgate regulations. The Board established a position of "Support" for the prior version.

The new version of the bill would eliminate the need for a new license type and would allow the board to determine in what manner these applications should be expedited through regulations.

STAFF RECOMMENDATION: Support

l. AB 2570 (Hill) Licensees: Settlement Agreements

Introduced: February 24, 2012
Location: Senate Judiciary (6/18/12)

There has been no change in this measure since the board established its position of "Oppose Unless Amended" at the May 1, 2012 Board Meeting.

Summary: This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards, as specified, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board. The board supported this provision.

The bill would also prohibit a board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil action to pay additional moneys to the benefit of any plaintiff in the civil action. The board opposed this provision.

Since the May Board Meeting, staff has had discussions with the author's staff, who do not share the board's perspective. Staff has been advised that amendments are forthcoming, but the board has not received language to specify what those amendments will be. Staff will continue to monitor this measure.

m. SB 1095 (Rubio) Surgical and Outpatient Clinics

Introduced: February 16, 2012
Location: Senate Appropriations (Fiscal: yes)
Status: June 26 – Set for Hearing in Assembly Health

Summary: SB 1095 would expand the definition of a clinic in Section 4190 to include not only surgical clinics licensed by the CDPH under H&SC Section 1204, but also to accredited outpatient settings and to Medicare certified ambulatory surgical centers, as specified. SB 1095 would provide that board licensure is optional, and that the board is authorized to inspect only those clinics which are licensed by the board. A clinic licensed by the board would be able to comingle the drug stock of the clinic and would authorize the clinic to purchase drugs at wholesale. SB 1095 would provide that

nothing in the article shall preclude a physician and surgeon from dispensing dangerous drugs as provided in B&PC Section 4170.

The board established a position of Oppose Unless Amended at the May 2012 Board Meeting. A copy of the board's position letter is attached. Since that time, staff has been working with the author's office and the sponsors to resolve concerns among the stakeholders. The board is expecting an amended bill to be in print very soon. Should the amendments reflect areas of consensus between the board and the author, staff would recommend that the board change its position to Support.

n. SB 1481 (Negrete McLeod) Clinical Laboratories: Community Pharmacies

Introduced: June 13, 2012
Location: June 26 – Set for Hearing in Assembly Health
Board Position: Support (2/24/12 version)

Summary: This bill would exempt from clinical laboratory licensing requirements and regulations and would limit a community pharmacy to provide only blood glucose, hemoglobin A1c, or cholesterol tests classified as waived under CLIA, and approved by the FDA for sale to the public without a prescription in the form of an over-the-counter test kit, as specified. The current version also requires a pharmacy that obtains a CLIA certificate of waiver, to notify the public health officer of the county in which the pharmacy is located, that the pharmacy is performing those tests.

The board established a SUPPORT position at the May 1st Board Meeting.

STAFF RECOMMENDATION: Maintain Support for current version

Other

o. AB 2369 (Valadao) Prisoners: Pharmacy Services

Introduced: June 14, 2012
Location: Re-referred to Assembly Health
Status: No hearing set as of 6/20/12

Summary: Existing law authorizes the Department of Corrections and Rehabilitation to maintain and operate a comprehensive pharmacy services program for facilities under the jurisdiction of the DCR that is cost effective and efficient, and that may incorporate a requirement to use "less expensive" medications. AB 2369 does not seek to modify existing Pharmacy Law. The board considered the introduced version of the bill (2/24/12) which required that "generic" medications be specified; however, the amended version of the bill specifies that "less expensive" medications be specified. The board has not taken a position on this measure.

STAFF RECOMMENDATION: None

p. SB 1185 (Price) Centralized Intelligence Partnership Act

Last Amend: May 29, 2012
Status: July 2, 2012 – Hearing in ASM Revenue & Taxation

Summary: This bill would create a Centralized Intelligence Partnership ("partnership") as a pilot program – until January 1, 2018 – for the purpose of combating the underground economy. This partnership would institutionalize collaboration among state agencies, with a key element being to authorize and facilitate data and intelligence sharing among the partnership and state agencies. The partnership shall consist of the Employment Development Department, the Franchise Tax Board and the State Board of Equalization. The Department of Consumer Affairs is one of six state agencies designated that may participate in the pilot program in an advisory capacity. Should the DCA wish to participate, the DCA may provide a representative to the advisory committee, which shall meet at least quarterly. The bill in its current form authorizes participating agencies to exchange intelligence, data, documents, information, complaints, leads, etc. SB 1185 specifies that the partnership shall report to the Legislature, and specifies the frequency and content of those reports.

Agenda Item A.1

Legislation Report

Board-Sponsored Legislation for 2012

BILL NUMBER: SB 1575 AMENDED
BILL TEXT

AMENDED IN ASSEMBLY JUNE 12, 2012
AMENDED IN SENATE APRIL 16, 2012

INTRODUCED BY Committee on Business, Professions and Economic Development (Senators Price (Chair), Corbett, Correa, Emmerson, Hernandez, Negrete McLeod, Strickland, Vargas, and Wyland)

MARCH 12, 2012

An act to amend Sections *1640,* 1934, 1950.5, 2021, 2064, 2184, 2220, 2424, 2516, 2518, *2570.13,* 2904.5, 3057.5, 3742, 3750, 3750.5, 4209, ~~4600, 4601, 4603.7, 4612,~~ 4980.04, 4980.34, *4980.397,* 4980.398, 4980.399, *4980.40,* 4980.43, 4980.44, 4980.48, *4980.50,* 4980.78, 4980.80, *4984.01,* 4984.4, *4984.7, 4984.72,* 4989.16, 4989.42, *4992.05,* 4992.07, 4992.09, *4992.1, 4996.1, 4996.3, 4996.4,* 4996.6, *4996.28,* 4999.22, 4999.32, *4999.45,* 4999.46, *4999.50, 4999.52, 4999.53, 4999.55,* 4999.57, 4999.58, 4999.59, 4999.62, *4999.63, 4999.64,* 4999.76, 4999.90, *4999.100,* 4999.106, and 4999.120 of, to add Sections 144.5, 1902.2, 1942, 1958.1, and 4300.1 to *, and to* repeal Section 1909.5 of, ~~and to repeal and amend Section 4999.45 of,~~ the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 1575, as amended, Committee on Business, Professions and Economic Development. Professions and vocations.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs.

(1) Under existing law, specified professions and vocations boards are required to require an applicant to furnish to the board a full set of fingerprints in order to conduct a criminal history record check.

This bill would authorize such a board to request, and would require a local or state agency to provide, certified records of, among other things, all arrests and convictions needed by a board to complete an applicant or licensee investigation. By imposing additional duties on local agencies, the bill would impose a state-mandated local program.

(2) Existing law, the Dental Practice Act, provides for the licensure and regulation of the practice of dentistry by the Dental Board of California within the Department of Consumer Affairs. Existing law establishes the Dental Hygiene Committee of California under the jurisdiction of the board and provides for the licensure and regulation of the practice of dental hygienists by the committee.

This bill would require dental hygienists, upon initial licensure and renewal, to report their employment status to the committee and would require that information to be posted on the committee's Internet Web site. This bill would also require an approval dental hygiene education program to register extramural dental facilities, as defined, with the committee.

Existing law provides that a dental hygienist may have his or her license suspended or revoked by the board for committing acts of unprofessional conduct, as defined.

This bill would include within the definition of unprofessional conduct the aiding or abetting of the unlicensed or unlawful practice of dental hygiene ~~and knowingly failing to follow infection control guidelines, as specified~~ .

Existing law authorizes the committee to deny an application for licensure or to revoke or suspend a license for specified reasons.

This bill would require the committee to deny a license or renewal of a license to any person who is required by law to register as a sex offender.

Existing law authorizes the Dental Board of California to issue a special permit to persons meeting certain requirements, including furnishing satisfactory evidence of having graduated from a dental college.

This bill would allow that requirement to also be met through completion of an accredited advanced education program.

(3) Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Under existing law, the board issues a physician and surgeon's certificate to a licensed physician and surgeon. Existing law provides for the licensure and regulation of the practice of podiatric medicine by the California Board of Podiatric Medicine within the Medical Board of California.

Existing law requires the Medical Board of California and the California Board of Podiatric Medicine to provide written notification by certified mail to any physician and surgeon or podiatrist who does not renew his or her license within 60 days of expiration.

This bill would require the Medical Board of California and the California Board of Podiatric Medicine to provide that written notification either by certified mail or by electronic mail if requested by the licensee. The bill would require the Medical Board of California to annually send an electronic notice to all licensees and applicants requesting confirmation that his or her electronic mail address is current.

Existing law authorizes the Medical Board of California to take action against all persons guilty of violating the Medical Practice Act. Existing law requires the Medical Board of California to enforce and administer various disciplinary provisions as to physician and surgeon certificate holders.

This bill would specify that those certificate holders include those who hold certificates that do not permit them to practice medicine, such as, but not limited to, retired, inactive, or disabled status certificate holders.

(4) Existing law, the Licensed Midwifery Practice Act of 1993, provides for the licensure and regulation of the practice of licensed midwifery by the Medical Board of California. A violation of the act is a crime. Under existing law, these licenses are subject to biennial renewal that includes the payment of a specified fee and the completion of specified continuing education.

This bill would exempt a licensee from those renewal requirements if the licensee has applied to the board and has been issued a retired status license. The bill would prohibit the holder of a retired status license from engaging in the practice of midwifery. Because a violation of that prohibition would constitute a crime, the bill would impose a state-mandated local program.

(5) Existing law, the Occupational Therapy Practice Act, requires the California Board of Occupational Therapy to ensure proper supervision of occupational therapy assistants and aides. An aide is required to be supervised by an occupational therapist.

This bill would also provide for an aide to be supervised by an occupational therapy assistant.

~~(5)~~

(6) Existing law, the Psychology Licensing Law, provides for the licensure and regulation of psychologists by the Board of Psychology. Existing law provides that a licensed psychologist is a health care practitioner for purposes of specified telehealth provisions that concern the delivery of health care via information and communication technologies.

This bill would instead provide that a licensed psychologist is a health care provider subject to those telehealth provisions.

~~(6)~~

(7) Existing law, the Respiratory Care Practice Act, provides for the licensure and regulation of the practice of respiratory care by the Respiratory Care Board of California.

Under existing law, during the period of any clinical training, a student respiratory care practitioner is required to be under the direct supervision, as defined, of a person holding a valid and current license.

This bill would require such a student to be under the direct supervision of a person with a valid, current, and unrestricted license.

Existing law authorizes the board to order the denial, suspension, or revocation of, or the imposition of probationary conditions upon, a license for specified causes including a pattern of substandard care.

This bill would expand that provision to also include negligence in the licensee's practice as a respiratory care practitioner, or in any capacity as a health care worker, consultant, supervisor, manager or health facility owner, or as a party responsible for the care of another.

Existing law authorizes the board to deny, suspend, place on probation, or revoke the license of any applicant or licenseholder who has obtained, possessed, used, or administered to himself or herself, or furnished or administered to another, any controlled substances or dangerous drug, except as directed by a specified

health care provider.

This bill would also make illegally possessing any associated paraphernalia a ground for the denial, suspension, placing on probation, or revocation of a license.

~~(7)~~

(8) Existing law, the Pharmacy Law, provides for the California State Board of Pharmacy within the Department of Consumer Affairs, to license and regulate the practice of pharmacy.

Existing law authorizes the board to suspend or revoke a license if the holder has been convicted of certain crimes or has engaged in unprofessional conduct, as specified.

This bill would modify the practice requirements applicable to intern pharmacists. The bill would also provide that the board continues to have jurisdiction in a disciplinary action against a licensee, even if the license is expired, cancelled, forfeited, suspended, revoked, placed on retired status, or voluntarily surrendered.

~~(8) Existing law provides for the voluntary certification of massage practitioners and massage therapists by the California Massage Therapy Council. Existing law provides specified educational and other requirements for an applicant to obtain a massage therapy certificate.~~

~~This bill would set minimum educational hour and course requirements for an applicant to qualify to receive a massage therapy certificate. The bill would also define "operator of a massage business" for purposes of these provisions.~~

~~Existing law requires a certificate holder to display the certificate at his or her place of business.~~

~~This bill would require the certificate holder to display the original certificate at his or her place of business and to have the identification card, issued by the council, with him or her whenever providing massage therapy services. This bill would also require a massage therapist to surrender his or her identification card when his or her certificate is suspended or revoked.~~

~~Existing law authorizes a city, county, or city and county to require background checks of certain uncertified owners or operators of massage therapy establishments.~~

~~This bill would authorize that background check to include a criminal background check, including submission of fingerprints and employment history for the 10 preceding years.~~

~~Existing law authorizes a city, county, or city and county to charge certain massage businesses or establishments a business licensing fee, provided that the fee charged is no different than what is uniformly applied to other individuals and businesses providing professional services, as specified.~~

~~The bill would require that the licensing fee charged to massage businesses or establishments be no higher than those charged to other professions. The bill would also prohibit a city, county, or city and county from requesting information from those businesses or establishments that is different from that requested of others providing professional services.~~

(9) Under existing law, the Board of Behavioral Sciences is responsible for the licensure and regulation of marriage and family therapists, licensed educational psychologists, licensed clinical social workers, and licensed professional clinical counselors.

Under existing law, a license that is not renewed within 3 years after its expiration may not be renewed. However, the former licensee is authorized to apply for and obtain a new license if certain requirements are met, including, but not limited to, passing one or more current licensing examinations, as specified and submitting certain fees.

This bill would additionally require a former licensee to comply with the fingerprint requirements established by board regulation or as directed by the board. The bill would make other technical and clarifying changes.

Existing law makes various changes to the licensing and associated examination requirements for marriage and family therapists, clinical social workers, and professional clinical counselors, effective January 1, 2013.

This bill would delay the implementation of these and other related changes until January 1, 2014.

(10) Existing law, the Marriage and Family Therapist Act, with respect to applicants for licensure or registration by reciprocity or for those applicants who obtained education or experience outside of California that apply on and after January 1, 2014, existing law provides that education is substantially equivalent if certain requirements are met, including the completion of a course in California law and professional ethics.

This bill would require that course to be 18 hours in length.

For persons who apply for licensure between January 1, 2010, and December 31, 2013, existing law authorizes the board to issue a license to a person who holds a valid license from another state if certain requirements are met, including the completion of specified coursework or training. Existing law provides that an applicant who completed a specified course in law and professional ethics is required to complete an 18-hour course in California law and professional ethics.

This bill would instead specify that an 18-hour course in California law and professional ethics is only required if the above specified course in law and professional ethics does not meet certain requirements. The bill would make other technical changes to those provisions.

The bill would rename the act as the Licensed Marriage and Family Therapist Act.

(11) Existing law, the Licensed Professional Clinical Counselor Act, provides for the licensure and regulation of the practice of professional clinical counseling by the Board of Behavioral Sciences.

Under existing law, to qualify for registration, an intern applicant is required to meet certain qualifications. With respect to applicants for registration who began graduate study before August 1, 2012, and complete study on or before December 31, 2018, an applicant is required to complete a minimum of 18 contact hours of instruction in California law and professional ethics prior to registration as an intern.

This bill would describe the content of that instruction for professional clinical counselors.

Existing law authorizes the board to refuse to issue any registration or license, or to suspend or revoke the registration or license of any intern or licensed professional clinical counselor, if the applicant, licensee, or registrant has been guilty of unprofessional conduct that includes, but is not limited to, the conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of specified substances, or any combination thereof.

This bill would delete the conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of specified substances, or any combination thereof, from the list of what constitutes professional conduct. The bill would make it unprofessional conduct to willfully violate specified provisions governing patient access to health care records.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 144.5 is added to the Business and Professions Code, to read:

144.5.

Notwithstanding any other provision of law, a board described in Section 144 may request a local or state agency to provide certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation. The local or state agency shall provide those records to the board upon receipt of such a request.

SEC. 2. Section 1640 of the Business and Professions Code is amended to read:

1640.

Any person meeting all the following eligibility requirements may apply for a special permit:

(a) Furnishing satisfactory evidence of having a pending contract with a California dental college approved by the board as a full-time professor, an associate professor, or an assistant professor.

(b) Furnishing satisfactory evidence of having graduated from a dental college approved by the board*, or of having completed an advanced education program accredited by either the Commission on Dental Accreditation of the American Dental Association or a national accrediting body approved by the board*.

(c) Furnishing satisfactory evidence of having been certified as a diplomate of a specialty board or, in lieu thereof, establishing his or her qualifications to take a specialty board examination or furnishing satisfactory evidence of having completed an advanced educational program in a discipline from a dental college approved by the board.

(d) Furnishing satisfactory evidence of successfully completing an examination in California law and ethics developed and administered by the board.

(e) Paying a fee for applications as provided by this chapter.

SEC. 3. Section 1902.2 is added to the Business and Professions Code, to read:

1902.2.

(a) A licensee shall report, upon his or her initial licensure

provider*, or illegally possessed any associated paraphernalia*.

(b) Used any controlled substance as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or any dangerous drug as defined in Article 2 (commencing with Section 4015) of Chapter 9 of this code, or alcoholic beverages, to an extent or in a manner dangerous or injurious to himself or herself, or to others, or that impaired his or her ability to conduct with safety the practice authorized by his or her license.

(c) Applied for employment or worked in any health care profession or environment while under the influence of alcohol.

(d) Been convicted of a criminal offense involving the consumption or self-administration of any of the substances described in subdivisions (a) and (b), or the possession of, or falsification of a record pertaining to, the substances described in subdivision (a), in which event the record of the conviction is conclusive evidence thereof.

(e) Been committed or confined by a court of competent jurisdiction for intemperate use of or addiction to the use of any of the substances described in subdivisions (a), (b), and (c), in which event the court order of commitment or confinement is prima facie evidence of that commitment or confinement.

(f) Falsified, or made grossly incorrect, grossly inconsistent, or unintelligible entries in any hospital, patient, or other record pertaining to the substances described in subdivision (a).

SEC. 22. **Section 4209 of the Business and Professions Code is amended to read:**
4209.

Board of Pharmacy

(a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. *Intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours.*

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience*, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist*. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

SEC. 23. **Section 4300.1 is added to the Business and Professions Code, to read:**
4300.1.

Board of Pharmacy

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

SEC. 24. **Section 4980.04 of the Business and Professions Code is amended to read:**
4980.04.

This chapter shall be known and may be cited as the *Licensed* Marriage and Family Therapist Act.

SEC. 25. **Section 4980.34 of the Business and Professions Code is amended to read:**
4980.34.

It is the intent of the Legislature that the board employ its resources for each and all of the following functions:

(a) The licensing of marriage and family therapists, clinical social workers, *professional clinical counselors,* and educational psychologists.

(b) The development and administration of licensing examinations and examination procedures, as specified, consistent with prevailing standards for the validation and use of licensing and certification tests. Examinations shall measure knowledge and abilities demonstrably important to the safe, effective practice of the profession.

(c) Enforcement of laws designed to protect the public from incompetent, unethical, or unprofessional practitioners.

(d) Consumer education.

SEC. 26. **Section 4980.397 of the Business and Professions Code is amended to read:**
4980.397.

(a) Effective January 1, ~~2013~~*2014*, an applicant for licensure as a marriage and family therapist shall pass the following two examinations as prescribed by the board:

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER:	**SB 1575**	**VERSION:**	**June 20, 2012**
AUTHOR:	**Senate Committee on Business, Professions and Economic Development**		
SUBJECT:	**Professions and Vocations (Omnibus)**		
Board Position:	**Support**		

Affected Sections: Amends / Adds various sections of the Business and Professions Code related to Healing Arts, including:
Section 144.5 - Records
Section 4209 – Pharmacist Exam Applications; Certification of Intern Hours
Section 4300.1 – Board jurisdiction to proceed with discipline on a license

Current Status: In Assembly Appropriations – No hearing set as of 6/20/12

EXISTING LAW:

1. Provides for the licensure and regulation of a variety of healing arts professionals under various boards within the Department of Consumer Affairs, including the Board of Pharmacy.
2. Provides for the licensing, oversight and regulation of the practice of pharmacy by the Board of Pharmacy (Business and Professions Code Section 4000 et seq.)
    a. Authorizes the board to suspend or revoke a license if the holder has been convicted of certain crimes or has engaged in unprofessional conduct.
    b. Requires a pharmacist exam applicant who has been licensed as a pharmacist in another state for at least one year, as specified, to submit certification of licensure from the other state to satisfy the required 1,500 hours of intern experience required to sit for the exam.

THIS BILL:

1. Adds Section 144.5 to the Business and Professions Code to allow the board to request – and require a local or state agency to provide – certified records of arrests, convictions and other related documentation needed to complete an applicant or licensee investigation. [SECTION 1., p. 7] Note: Board staff have been advised that the Respiratory Care Board will be amending this provision out.

2. Amends Section 4209 related to pharmacist exam applicants to [SEC. 20, p. 22]

- **a.** Specify that an intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours; and,
- **b.** For the pharmacist exam applicant that has been licensed as a pharmacist in another state for at least one year, that he or she may submit certification of licensure from the other state to satisfy the 1,500 hours of intern experience required, so long as the applicant has obtained *a minimum of 900 hours* of pharmacy practice experience in a pharmacy as a pharmacist.

3. Adds Section 4300.1 to the Business and Professions Code to ensure the board's jurisdiction to commence or proceed with an investigation of, or action or disciplinary action against, a license or render a decision to suspend or revoke a license even if that license has been cancelled, forfeited, suspended, surrendered, placed on retired status, etc. [SEC. 21, p. 23]

COMMENTS:

October 2011 – The board approved the omnibus provisions to amend Section 4209
January 2012 – The board approved omnibus provisions to add Section 4300.1
May 2012 – Board established a position of SUPPORT

Agenda Item A.2

Legislation Report

Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

Agenda Item A.2

Legislation Report

a. Regulation of Dangerous Drugs and Devices

BILL NUMBER: AB 389 AMENDED
BILL TEXT

AMENDED IN SENATE JANUARY 17, 2012
AMENDED IN ASSEMBLY MARCH 30, 2011
AMENDED IN ASSEMBLY MARCH 15, 2011
AMENDED IN ASSEMBLY MARCH 7, 2011

INTRODUCED BY Assembly Member Mitchell
(Principal coauthor: Senator Pavley)

FEBRUARY 14, 2011

An act to add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic diseases.

LEGISLATIVE COUNSEL'S DIGEST

AB 389, as amended, Mitchell. Bleeding disorders.

Existing law, the Holden-Moscone-Garamendi Genetically Handicapped Person's Program, requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

This bill would impose specified requirements on providers of blood clotting products for home use, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce these provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Article 5 (commencing with Section 125286.10) is added to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, to read:

125286.10.

This article shall be known, and may be cited, as the Standards of Service for Providers of Blood Clotting Products for Home Use Act.

125286.15.

The Legislature hereby finds and declares all of the following:

(a) Hemophilia is a rare, hereditary, bleeding disorder affecting at least 4,000 persons in California and is a chronic, lifelong, and incurable, but treatable, disease.

(b) Von Willebrand disease is a human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand factor in human blood, which is a protein that helps clot blood. Von Willebrand disease is a chronic, lifelong, incurable, but treatable, disease affecting at least 360,000 Californians.

(c) Until the 1970s, people with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a shortened lifespan. More recently, the production of highly purified blood clotting factors has provided people with hemophilia and other bleeding disorders the opportunity to lead normal lives, free of pain and crippling arthritis.

(d) The preferred method of treatment of hemophilia today is intravenous injection, or infusion, of prescription blood clotting products several times per week, along with case management and specialized medical care at a federally designated regional hemophilia treatment center.

(e) Pharmacies and other entities specializing in the delivery of blood clotting products and related equipment, supplies, and services for home use form a growing enterprise in California.

(f) Timely access to federally designated regional hemophilia centers and appropriate products and services in the home, including infusion of blood clotting products and related equipment, and supplies and services for persons with hemophilia and other bleeding disorders, reduces mortality and bleeding-related hospitalizations according to the federal Centers for Disease Control and Prevention

and the Medical and Scientific Advisory Council of the National Hemophilia Foundation.

(g) Eligible persons with hemophilia or other bleeding disorders may receive treatment through the Genetically Handicapped Persons Program, the California Children's Services Program, and the Medi-Cal program.

(h) For the benefit of persons with hemophilia or other bleeding disorders, the purposes of this article are to do the following:

(1) Establish standards of service for entities that deliver blood clotting products and related equipment, supplies, and services for home use.

(2) Promote access to a full range of essential, cost-effective, lifesaving, blood clotting products and related equipment, supplies, and high-quality services for home use for persons with hemophilia and other bleeding disorders.

125286.20.

Unless the context otherwise requires, the following definitions shall apply for purposes of this article:

(a) "Assay" means the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug.

(b) "Ancillary infusion equipment and supplies" means the equipment and supplies required to infuse a blood clotting product into a human vein, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs.

(c) "Bleeding disorder" means a medical condition characterized by a deficiency or absence of one or more essential blood clotting proteins in the human blood, often called "factors," including all forms of hemophilia and other bleeding disorders that, without treatment, result in uncontrollable bleeding or abnormal blood clotting.

(d) "Blood clotting product" means an intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, factor VII, factor VIIa, factor VIII, and factor IX products, von Willebrand factor products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

(e) "Emergency" means care as defined in Section 1317.1.

(f) "Hemophilia" means a human bleeding disorder caused by a hereditary deficiency of the factors I, II, V, VIII, IX, XI, XII, or XIII blood clotting protein in human blood.

(g) "Hemophilia treatment center" means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding specifically for the treatment of patients with bleeding disorders from federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.

(h) "Home use" means infusion or other use of a blood clotting product in a place other than a state-recognized hemophilia treatment center or other clinical setting. Places where home use occurs include, without limitation, a home or other nonclinical setting.

(i) "Patient" means a person needing a blood clotting product for home use.

(j) (1) "Provider of blood clotting products for home use" means all the following pharmacies, except as described in Section 125286.35, that dispense blood clotting factors for home use:

(A) Hospital pharmacies.

(B) Health system pharmacies.

(C) Pharmacies affiliated with hemophilia treatment centers.

(D) Specialty home care pharmacies.

(E) Retail pharmacies.

(2) The providers described in this subdivision shall include a health care service plan and all its affiliated providers if the health care service plan exclusively contracts with a single medical group in a specified geographic area to provide professional services to its enrollees.

125286.25.

Each provider of blood clotting products for home use shall meet all of the following requirements:

(a) Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient and the medical and psychosocial management thereof, including, but not limited to, home therapy.

(b) Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors.

(c) Maintain 24-hour on-call service seven days a week for every day of the year, adequately screen telephone calls for emergencies, acknowledge all telephone calls within one hour or less, and have

access to knowledgeable pharmacy staffing on call 24 hours a day, to initiate emergency requests for clotting factors.

(d) Have the ability to obtain all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges (low, medium, and high, as applicable) and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained.

(e) Supply all necessary ancillary infusion equipment and supplies with each prescription, as needed.

(f) Store and ship, or otherwise deliver, all blood clotting products in conformity with all state and federally mandated standards, including, but not limited to, the standards set forth in the product's approved package insert (PI).

(g) Upon receiving approved authorization for a nonemergency prescription, provided manufacturer supply exists, ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less for established and new patients.

(h) Upon receiving approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, deliver prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport.

(i) Provide patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery and respond to these calls within a reasonable time period.

(j) Provide patients with notification of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of the provider of blood clotting products for home use receiving notification and participate in the National Patient Notification System for blood clotting product recalls.

(k) Provide language interpretive services over the telephone or in person, as needed by the patient.

(l) Have a detailed plan for meeting the requirements of this article in the event of a natural or manmade disaster or other disruption of normal business operations.

(m) Provide appropriate and necessary recordkeeping and documentation as required by state and federal law and retain copies of the patient's prescriptions.

(n) Comply with the privacy and confidentiality requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

125286.30.

The California State Board of Pharmacy shall administer and enforce this article.

125286.35.

Nothing in this article shall apply to either hospital pharmacies or health system pharmacies that dispense blood clotting products due only to emergency, urgent care, or inpatient encounters, or if an inpatient is discharged with a supply of blood clotting products for home use.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER:	**AB 389**	**VERSION:**	**Amended January 17, 2012**
AUTHOR:	**Mitchell**	**SPONSOR:**	**Hemophelia Council of California**

BOARD POSITION: **Oppose** *(Reaffirmed January 2012)*

SUBJECT: **Bleeding Disorders: Blood Clotting Products**

Affected Sections: Add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code

Current Status: In the Senate. On Third Reading File (6/21/12)

EXISTING LAW:

1. Establishes the Holden-Moscone-Garamendi Genetically Handicapped Person's Program within the Department of Health Care Services. [H&SC § 125125]
2. Requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically disabling conditions, including hemophilia. [H&SC § 125130]
3. Requires the Division of Licensing of the Medical Board of California to establish continuing education requirements for physicians and surgeons as specified and sets forth the criteria that the division shall use in considering courses. [B&PC § 2191]

THIS BILL WOULD:

1. Add Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act that includes the following:
   a. Findings and declarations about bleeding disorders, history of and treatment of such disorders, pharmacies role in the delivery of products, identification of persons eligible for treatment through various programs, and states that this article is necessary for the benefit of persons with bleeding disorders to establish standards of service and to promote cost effective, life saving products for home use.
   b. Defines various terms for purposes of this article including:
      i. "assay"
      ii. "ancillary infusion equipment and supplies"
      iii. "bleeding disorder"
      iv. "blood clotting product
      v. "emergency"

vi. “hemophilia”
vii. “hemophilia treatment center”
viii. “home use”
ix. “patient”
x. “provider of blood clotting products” to mean specified pharmacies that dispense blood clotting factors for home use, unless excepted
    1. Hospital pharmacies
    2. Health system pharmacies
    3. Pharmacies affiliated with hemophilia treatment centers
    4. Specialty home care pharmacies
    5. Retail pharmacies
xi. And that the above providers shall include a health care service plan and all its affiliated providers if the health care service plan exclusively contracts with a single medical group in a specified geographic area to provide professional services to its enrollees.

c. Requires that each provider, as defined above, meet the following requirements:
    i. Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescriber and ensure quality care.
    ii. Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to know when patients have an appropriate supply of product on hand as well and understanding about proper storage and refrigeration.
    iii. Maintain 24-hour on-call service seven days a week, 365 days a year.
    iv. Have the ability to obtain all brands of the products approved by the FDA in multiple assay ranges as specified.
    v. Supply all necessary ancillary infusion equipment and supplies as needed.
    vi. Store, ship, or otherwise deliver, all products in conformity with state and federally mandated standards.
    vii. Ship product within two business days to a patient for a nonemergency prescription.
    viii. For emergencies, deliver products, ancillary equipment, supplies and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, or within one day for patients living outside that area.
    ix. Provide contact information to a patient to report problems with delivery.
    x. Provide patient with product recall and withdrawal notifications within 24 hours.
    xi. Provide language interpretive service via phone or in person, as needed.
    xii. Have a detailed plan in the event of a natural or manmade disaster.
    xiii. Provide appropriate record keeping.
    xiv. Comply with HIPAA requirements.

2. Requires the California Board of Pharmacy to administer and enforce this article.

AUTHOR'S INTENT:
According to the author's office, "AB 389 will establish standards of service for pharmacies that deliver blood clotting products and related equipment, supplies, and services for home use and would promote access to a full range of essential, cost effective, life-saving, blood clotting products and related equipment, supplies for home use for people who have hemophilia, von Willebrand disease and other bleeding disorders."

COMMENTS:
Many of these provisions in AB 389 are currently the standard of practice, but are not codified. This measure specifies that the Board of Pharmacy will enforce the provisions of this bill. The board could fulfill this mandate through routine inspections of pharmacies and others under the board's jurisdiction as well as investigation of consumer complaints received. The board would already have jurisdiction to investigate consumer complaints involving poor service or product delivery that resulted in either patient harm or the potential for harm. We are unaware of any such complaints received by the board.

There are potential challenges in enforcing some of these provisions. Specifically, the board may not be in a position to assess the clinical experience of the provider to ensure they have sufficient experience to know when patients have an appropriate supply of clotting factor on hand as required.

A previous version of this bill contained a provision requiring the Licensing Division of the Medical Board to consider requiring a continuing education course on bleeding disorders. This provision was amended out of the measure on March 30, 2011. Previous provisions related to the requirement that a provider provide home nursing services were amended out the measure on January 17, 2012.

PRIOR BOARD DISCUSSION and ACTION:
The board opposed the measure in August 2011. The board reaffirmed this position at the January 2012 Board Meeting.

In its letter of opposition (8/18/11), the board cited the lack of a compelling need to establish codified provisions for a medical condition which could result in a more complex series of provisions that could actually impair patient care and compliance with the already extensive provisions in place to regulate pharmacy care. The board also stated that it was not aware of any problems in the care provided by pharmacies to patients with bleeding disorders based on the lack of complaints in this area.

FISCAL/ECONOMIC IMPACT:
We anticipate a portion of an inspector PY will be necessary to ensure compliance with these provisions. This workload could possibly be absorbed if the board is able to fill all authorized inspector positions. However, because of the bill's specificity and the need for close monitoring of these provisions, the board would need to do frequent inspections. Because the specialty pharmacies are not required to have a separate license, nor are they required to notify the board that they provide such services, performing inspection on all pharmacies that provide these services would be a challenge.

PREVIOUS/RELATED LEGISLATION
SB 1594 (Steinberg, 2007) would have established standards for providers of blood clotting products. The board had a "Watch" position on the bill. The measure later died after being placed on the Senate Appropriations Suspense File and never passed out of the house of origin.

SB 971 (Pavely, 2010) introduced legislation similar to this proposal. The board did not have a position on this bill. This bill was vetoed by the governor.

> "I am returning Senate Bill 971 without my signature. This bill is unnecessary and attempts to create additional standards that are already being adequately enforced through other regulatory and administrative mechanisms. Since the current standards of practice for blood clotting products and service are already being met through state and federal pharmacy laws, voluntary compliance and existing state contract provisions, it is unclear what problem this bill seeks to address. For these reasons, I am unable to sign this bill."

SUPPORT/OPPOSITION:
Support
Hemophilia Council of California (Sponsor)
Accredo Health Group Inc.
Baxter Healthcare
California Academy of Family Physicians
California Medical Association
California Pharmacists Association
California Society of Health System Pharmacists
Community Healthcare Services
CSL Behring
DLA Piper
DRG Pharmacy LLC
Federal Hemophilia Treatment Centers, Region XI
Grifols Inc.
Hemophilia Foundation of Northern California
Herndon Pharmacy
Meyer Family Cellars
National Cornerstone Healthcare Services Inc.
Pfizer Inc.
Red Chip Enterprises
Talecris Biotherapeutics
UC Davis Medical Center
Walgreens

Oppose
Board of Pharmacy

HISTORY:

Date	Action
2012	
Jan. 18	Read second time. Ordered to third reading.
Jan. 17	From inactive file. Ordered to second reading. Read second time and amended. Ordered to second reading.
2011	
Sept. 1	From Special Consent Calendar pursuant to Joint Rule 22.2. Ordered to third reading. Ordered to inactive file at the request of Senator Pavley.
Aug. 31	Ordered to special consent calendar.
Aug. 23	Read second time. Ordered to third reading.
Aug. 22	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
Aug. 15	In committee: Hearing postponed by committee.
July 6	From committee: Do pass and re-refer to Com. on APPR. (Ayes 8. Noes 0.) (July 6). Re-referred to Com. on APPR.
June 23	From committee: Do pass and re-refer to Com. on B., P. & E.D. with recommendation: to consent calendar. (Ayes 8. Noes 0.) (June 22). Re-referred to Com. on B., P. & E.D.
June 8	In committee: Hearing postponed by committee.
May 12	Referred to Coms. on HEALTH and B., P. & E.D.
Apr. 28	In Senate. Read first time. To Com. on RLS. for assignment.
Apr. 28	Read third time. Passed. Ordered to the Senate. (Ayes 78. Noes 0. Page 1127.)
Apr. 14	Read second time. Ordered to third reading.
Apr. 13	From committee: Do pass. (Ayes 12. Noes 3.) (April 13).
Apr. 6	From committee: Do pass and re-refer to Com. on APPR. (Ayes 15. Noes 3.) (April 5). Re-referred to Com. on APPR.
Mar. 31	Re-referred to Com. on HEALTH.
Mar. 30	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 22	From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 9. Noes 0.) (March 22). Re-referred to Com. on HEALTH.
Mar. 16	Re-referred to Com. on B., P. & C.P.
Mar. 15	From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
Mar. 8	Re-referred to Com. on B., P. & C.P.
Mar. 7	From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
Feb. 24	Referred to Com. on B., P. & C.P.
Feb. 15	From printer. May be heard in committee March 17.
Feb. 14	Read first time. To print.

BILL NUMBER: AB 1442 AMENDED
BILL TEXT

AMENDED IN SENATE JUNE 14, 2012
AMENDED IN ASSEMBLY MARCH 27, 2012
AMENDED IN ASSEMBLY FEBRUARY 6, 2012

INTRODUCED BY Assembly Member Wieckowski
(Coauthors: Assembly Members Allen and Williams)

JANUARY 4, 2012

An act to amend Sections 117935, 117945, 117960, 118000, 118040, and 118165 of, and to add Sections 117637, 117748, ~~and~~ 118032 *, and 118033* to, the Health and Safety Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 1442, as amended, Wieckowski. Pharmaceutical waste.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Existing law requires that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. Violation of these provisions of law is a crime.

This bill would define pharmaceutical waste for purposes of the Medical Waste Management Act, and would ~~authorize~~ *exempt* a ~~medical~~ *pharmaceutical* waste generator or parent organization that employs health care professionals who generate ~~pharmaceuticals to apply to the enforcement agency for a~~ pharmaceutical *waste from specified medical* waste hauling ~~exemption~~ *requirements* if the generator, health care professional, or parent organization retains specified documentation and meets specified requirements and if the facility receiving the medical waste retains specified documentation *and meets specified requirements* . The bill would authorize pharmaceutical waste to be transported by the generator or health care professional who generated the pharmaceutical waste, a staff member of the generator or health care professional, or common carrier, as defined, pursuant to these provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 117637 is added to the Health and Safety Code, to read:

117637.

"Common carrier" means either of the following:

(a) A person or company that has a United States Department of Transportation number issued by the Federal Motor Carrier Safety Administration and is registered with the Federal Motor Carrier Safety Administration as a for-hire property carrier.

(b) A person or company that has a motor carrier of property permit issued by the Department of Motor Vehicles pursuant to the Motor Carriers of Property Permit Act (Division 14.85 (commencing with Section 34600) of the Vehicle Code) and, if applicable, a carrier identification number issued by the Department of the California Highway Patrol pursuant to Section 34507.5 of the Vehicle Code.

SEC. 2. Section 117748 is added to the Health and Safety Code, to read:

117748.

(a) "Pharmaceutical waste" means any pharmaceutical, as defined in Section 117747, that for any reason may no longer be sold or dispensed for use as a drug.

(b) For purposes of this part, "pharmaceutical waste" does not include any pharmaceutical that is outdated or nonsalable and is being returned to a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, that is licensed both as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4160 of the Business and Professions Code and as a permitted transfer station pursuant to Section 117775, for possible manufacturer credit.

SEC. 3. Section 117935 of the Health and Safety Code is amended to read:

117935.

Any small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person~~.~~

~~(b) The business address of the person.~~

~~(c) The type of business.~~

~~(d) The types, and the estimated average monthly quantity, of medical waste generated.~~

~~(e) The type of treatment used onsite.~~

~~(f)~~

.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite.

(f)

The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, ~~or~~ the name of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment and disposal~~.~~

~~(g)~~

, and, if applicable, the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal pursuant to Section 118032.

(g)

A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable~~.~~

~~(h)~~

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(h)

The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable~~.~~

~~(i)~~

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(i)

A statement certifying that the information provided is complete and accurate~~.~~*.*

SEC. 4. Section 117945 of the Health and Safety Code is amended to read:

117945.

Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

(a) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.

(b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, ~~and~~ the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030*, and, if applicable, the name of the common carrier transporting pharmaceutical waste pursuant to Section 118032*. The small quantity generator shall maintain these records for not less than two years.

SEC. 5. Section 117960 of the Health and Safety Code is amended to read:

117960.

Any large quantity generator required to register with the enforcement agency pursuant to Section 117950 shall file with the

enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person~~.~~

~~(b) The business address of the person.~~

~~(c) The type of business.~~

~~(d)~~

.

(b) The business address of the person.

(c) The type of business.

(d)

The types, and the estimated average monthly quantity, of medical waste generated~~.~~

~~(e)~~

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(e)

The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, including incinerators or steam sterilizers or other treatment facilities as determined by the enforcement agency, the treatment capacity of the onsite treatment facility~~.~~

~~(f)~~

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(f)

The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable~~.~~

~~(g)~~

, and, if applicable, the name and business address of the common carrier transporting pharmaceutical waste pursuant to Section 118032.

(g)

The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe, if applicable~~.~~

~~(h)~~

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(h)

The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable~~.~~

~~(i)~~

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(i)

An emergency action plan complying with regulations adopted by the department~~.~~

~~(j)~~

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(j)

A statement certifying that the information provided is complete and accurate~~.~~*.*

SEC. 6. Section 118000 of the Health and Safety Code is amended to read:

118000.

(a) Except as otherwise exempted pursuant to Section 118030 *or 118032*, all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118025) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate, upon demand, to any enforcement agency personnel or authorized employee of the Department of the California Highway Patrol~~.~~

~~(b)~~

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(b)

Except for small quantity generators transporting medical waste pursuant to Section 118030 *or small quantity generators or common carriers transporting pharmaceutical waste pursuant to Section 118032*, medical waste shall be transported to a permitted offsite medical waste treatment facility or a permitted transfer station in leak-resistant and fully enclosed rigid secondary containers that are then loaded into an enclosed cargo body~~.~~

~~(c)~~

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(c)

A person shall not transport medical waste in the same vehicle with other waste unless the medical waste is separately contained in rigid

containers or kept separate by barriers from other waste, or unless all of the waste is to be handled as medical waste in accordance with this part.

~~(d)~~

(d)

Medical waste shall only be transported to a permitted medical waste treatment facility, or to a transfer station or another registered generator for the purpose of consolidation before treatment and disposal, pursuant to this part.

~~(e)~~

(e)

Facilities for the transfer of medical waste shall be annually inspected and issued permits in accordance with the regulations adopted pursuant to this part.

~~(f)~~

(f)

Any persons manually loading or unloading containers of medical waste shall be provided by their employer at the beginning of each shift with, and shall be required to wear, clean and protective gloves and coveralls, changeable lab coats, or other protective clothing. The department may require, by regulation, other protective devices appropriate to the type of medical waste being handled.

SEC. 7. Section 118032 is added to the Health and Safety Code, to read:

118032.

A pharmaceutical waste generator or parent organization that employs health care professionals who generate pharmaceutical waste is exempt from the requirements of subdivision (a) of Section 118000 if all of the following requirements are met:

(a) The generator or parent organization has on file one of the following:

(1) If the generator or parent organization is a small quantity generator required to register pursuant to Chapter 4 (commencing with Section 117915), a medical waste management plan prepared pursuant to Section 117935.

(2) If the generator or parent organization is a small quantity generator not required to register pursuant to Chapter 4 (commencing with Section 117915), the information document maintained pursuant to subdivision (a) of Section 117945.

(3) If the generator or parent organization is a large quantity generator, a medical waste management plan prepared pursuant to Section 117960.

(b) The generator or health care professional who generated the pharmaceutical waste transports the pharmaceutical waste himself or herself, or directs a member of his or her staff to transport the pharmaceutical waste to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal, or contracts with a common carrier to transport the pharmaceutical waste to a permitted medical waste treatment facility or transfer station.

(c) Except as provided in subdivision (d), all of the following requirements are met:

(1) Prior to shipment of the pharmaceutical waste, the generator notifies the intended destination facility that it is shipping pharmaceutical waste to it and provides a copy of the tracking document, as specified in Section 118040.

(2) The generator and the facility receiving the pharmaceutical waste maintain the tracking document, as specified in Section 118040.

(3) The facility receiving the pharmaceutical waste notifies the generator of the receipt of the pharmaceutical waste shipment and any discrepancies between the items received and the tracking document, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(4) The generator notifies the enforcement agency of any discrepancies between the items received and the tracking document, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(d) (1) Notwithstanding subdivision (c), if a health care professional who generates pharmaceutical waste returns the pharmaceutical waste to the parent organization for the purpose of consolidation before treatment and disposal over a period of time, a single-page form or multiple entry log may be substituted for the tracking document, if the form or log contains all of the following information:

(A) The name of the person transporting the pharmaceutical waste.

(B) The number of containers of pharmaceutical waste. This clause does not require any generator to maintain a separate pharmaceutical waste container for every patient or to maintain records as to the specified source of the pharmaceutical waste in any container.

(C) The date that the pharmaceutical waste was returned.

(2) The form or log described in paragraph (1) shall be maintained in the files of the health care professional who generates the pharmaceutical waste and the parent organization or another health care facility that receives the pharmaceutical waste.

(3) This subdivision does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility, provided the form or log meets the requirements specified in paragraphs (1) and (2).

SEC. 8. Section 118033 is added to the Health and Safety Code, to read:

118033.

The pharmaceutical waste that is separated from medical waste by the generator shall be maintained in a manner to secure the pharmaceutical waste contents from access by unauthorized individuals. Any suspected or confirmed tampering of, unauthorized access to, or loss of this pharmaceutical waste shall be reported to the appropriate state licensing authority.

SEC. 9. Section 118040 of the Health and Safety Code is amended to read:

118040.

(a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years~~.~~

~~(b)~~

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(b)

The tracking document shall include, but not be limited to, all of the following ~~information:~~

~~(1)~~

information:

(1)

The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 118030~~.~~

~~(2) The type and quantity of medical waste transported.~~

~~(3)~~

.

(2) The type of pharmaceutical waste transported and the quantity or aggregate weight of pharmaceutical waste transported.

(3)

The name, address, and telephone number of the generator~~.~~

~~(4)~~

.

(4)

The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste~~.~~

~~(5)~~

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(5)

The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility~~.~~

~~(c)~~

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(c)

Any hazardous waste transporter or generator transporting medical waste in a vehicle shall have a tracking document in his or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information concerning the medical waste that the enforcement agency may require~~.~~

~~(d)~~

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(d)

A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original tracking document~~.~~

~~(e)~~

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(e)

Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department~~.~~

~~(f)~~

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(f)

Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the medical waste is crossing an international border, the medical waste shall be treated in accordance with Chapter 8 (commencing with Section 118215) prior to being transported out of the state~~.~~*.*

SEC. 10. Section 118165 of the Health and Safety Code is amended to read:

118165.

On and after April 1, 1991, all persons operating a medical waste treatment facility shall maintain individual records for a period of three years and shall report or submit to the enforcement agency upon request, all of the following information:

(a) The type of treatment facility and its capacity~~.~~

~~(b) All treatment facility operating records.~~

~~(c)~~

.

(b) All treatment facility operating records.

(c)

Copies of the tracking documents for all medical waste it receives for treatment from offsite ~~generators or from~~ *generators,* hazardous waste haulers~~.~~*, or, pursuant to Section 118032, common carriers.*

SEC. 11.

No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER:	**AB 1442**	**VERSION:**	**As Amended June 14, 2012**
AUTHOR:	**Weickowski**	**SPONSOR:**	**EXP Pharmaceutical Services**

BOARD POSITION: Oppose Unless Amended

SUBJECT: **Common Carriers to Transport Pharmaceutical Waste**

Affected Sections: Add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code

Current Status: **July 2, 2012** - Scheduled for hearing in Senate Environmental Quality Committee

EXISTING LAW:

1. Establishes the Medical Waste Management Act (MWMA), administered by the State Department of Public Health (DPH) (Health and Safety Code § 117600 et seq.) to include
    a. Requirements for Medical Waste / Small Quantity Generators (Health and Safety Code § 117915-117945), to include
        i. Minimum information required to be contained in a small quantity generator's medical waste management plan (H&SC § 117935)
        ii. Records that must be maintained by a small quantity generator that is not required to register (H&SC § 117945)
    b. Requirements for Medical Waste / Large Quantity Generators (Health and Safety Code § 117950-117995)
    c. The Licensing and Oversight of Medical Waste Haulers, requirements and exemptions (Health and Safety Code § 118000 et seq.)
    d. Recordkeeping Requirements for the Medical Waste Treatment Facilities (Health and Safety Code § 118165)
2. Provides for the licensure and regulation of "reverse distributors" by the California State Board of Pharmacy (defined at Business and Professions Code § 4040.5)
3. Provides for the management of hazardous waste by the Department of Toxic Substances Control (Health and Safety Code Section 25100 et seq.) and related regulations (11 CCR starting at Section 6626.1)

THIS BILL WOULD:

1. Amend the Medical Waste Management Act to allow for the legal handling and transportation of pharmaceutical waste by a common carrier.

   Specifically, AB 1442 would

   a. Add a definition of "common carrier." [SEC.1. Section 117637]

   b. Add a definition of "pharmaceutical waste" as any pharmaceutical (defined at H&SC 117747) that for any reason may no longer be sold or dispensed for use as a drug, excluding those pharmaceuticals that are being returned to a reverse distributor (licensed by the Board) and that also is licensed as permitted transfer station (under H&SC § 117775). [SEC.2. Section 117748]

   c. Require generators of pharmaceutical waste to include in its medical waste management plan the name of the common carrier used to transport the pharmaceutical waste.

   d. Exempt from requirements that specify the manner in which medical waste shall be transported to a medical waste treatment facility or permitted transfer station, those with a pharmaceutical waste hauling exemption, a small quantity generator transporting pharmaceutical waste, or a common carrier transporting pharmaceutical waste, as specified. [SEC.6. Section 118000(a) and (b)]

   e. Specify requirements under which a medical waste generator or parent organization that generates pharmaceutical waste may apply for a "pharmaceutical waste hauling exemption" to include specified recordkeeping requirements [SEC.7. Section 118032]

   f. Specify that tracking documents of a hazardous waste transporter or generator of medical waste also specify the quantity or aggregate weight of medical waste transported as well as advanced notice of the shipment of pharmaceutical waste via a common carrier. [SEC.8, Section 118040 §(b)(2)]

   g. Require that the records kept and maintained by Medical Waste Treatment Facilities also include tracking documents for generators of pharmaceutical waste. [Sec.9. Section 118165(c)]

   h. Specify that the pharmaceutical waste must be separated from the medical waste and maintained in a secure manner and establishes a notice requirement for suspected or confirmed tampering of the pharmaceutical waste.

AUTHOR'S INTENT:

According to the author, AB 1442 would allow healthcare facilities to ship all non-dispensable (unwanted) pharmaceuticals designated as "medical waste" via common carriers. The author states that a substantial portion of unwanted pharmaceuticals at healthcare facilities (not designated as 'hazardous' under federal law) must be handled as medical waste under state law, and the transportation costs associated with the disposal of that waste "encourages healthcare facilities to illegally dispose of the pharmaceuticals via the trash or sewer system."

The author further states that allowing healthcare facilities to utilize common carriers for the transportation of "all unwanted pharmaceuticals" simply makes sense.

COMMENTS:
Current law defines pharmacy waste as biohazardous waste, which in turn (in another code section) is designated as medical waste. The Medical Waste Management Act (MWMA) prescribes the methods for treating such waste because of the potential harm to public health and safety and the environment if not managed properly. The MWMA establishes rigorous management and tracking requirements for medical waste; including requiring the use of hazardous or medical waste haulers and strict manifesting requirements. Regulation of the MWMA is performed by the California Department of Public Health.

Under current law dangerous drugs being shipped through the traditional supply chain for dispensing are shipped to authorized entities in many instances by common carriers. In addition, drugs that are being returned to a reverse distributor for credit are also done so by common carrier.

In its current form, this proposal would make amendments to the MWMA to define pharmaceutical waste as a subset of medical waste and would allow for such waste to be transported by a common carrier. The proposal was amended to address many of the concerns identified by the board.

PRIOR BOARD DISCUSSION and ACTION:
During the May 2012 board meeting, members discussed this measure and some of the concerns the bill posed in the current form. These concerns discussed the need for controls in the movement of the drugs that are picked up and shipped. After discussion the board established an Oppose Unless Amended position.

RECENT UPDATES
Staff has worked with the author's office requesting changes to the legislation that will provide for the security of the pharmaceutical waste. The bill in its current form incorporates many of the changes requested. In light of the changes incorporated at the request of the board and the author's office commitment to working with the board, staff recommends that the board consider changing it's position on this bill to a neutral position.

PREVIOUS LEGISLATION
In the previous session, Senator Simitian authored SB 26, which sought to implement provisions for common carriers to pick up and transport pharmaceutical waste (drugs returned to the pharmacy by patients).

In dealing with drug take-back issues, the board has in the past sought amendments to Pharmacy Law that would have allowed pharmaceutical waste to be transported by a licensed integrated waste hauler, given sufficient recordkeeping. The board's proposal specified that a reverse distributor shall not accept the return of dangerous drugs that have been dispensed to patients, which are later returned by the patient to the pharmacy, and would also specify that – if these drugs were accepted by the pharmacy – the drugs shall only be handled by a licensed integrated waste hauler. The board's proposal specified recordkeeping requirements for drugs that were returned to a wholesaler or provided to a reverse distributor, to include:

- the quantity or weight of drugs returned
- the date the drugs were returned
- the names of the reverse distributors or wholesalers to whom the drugs were provided.

Also, records of drugs returned to a licensed integrated waste hauler shall specify

- the volume in weight or measurement of the pharmaceutical waste
- the date
- the name of the licensed integrated waste hauler

SUPPORT/OPPOSITION:

Support

EXP Pharmaceutical Services Corp.
Fremont Chamber of Commerce

HISTORY:

Date	Action
June 14	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. On E.Q.
June 14	Referred to Com. on E.Q.
May 31	In Senate. Read first time. To Com. on RLS. for assignment.
May 30	Read third time. Passed. Ordered to the Senate. (Ayes 78. Noes 0. Page 5088.)
May 25	From committee: Do pass. (Ayes 17. Noes 0.) (May 25). Read second time. Ordered to third reading.
Apr. 18	In committee: Set, first hearing. Referred to APPR. Suspense file.
Mar. 28	Re-referred to Com. on APPR.
Mar. 27	Read second time and amended.
Mar. 26	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 8. Noes 0.) (March 20).
Feb. 7	Re-referred to Com. on E.S. & T.M.
Feb. 6	From committee chair, with author's amendments: Amend, and re-refer to Com. on E.S. & T.M. Read second time and amended.
Jan. 26	Referred to Com. on E.S. & T.M.
Jan. 5	From printer. May be heard in committee February 4.
Jan. 4	Read first time. To print.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 18, 2012

The Honorable Bob Wieckowski
Member, California State Assembly
State Capitol, Room 4162
Sacramento, CA 95816

RE: AB 1442

Dear Assemblymember Wieckowski:

I regret to advise you that the Board of Pharmacy has taken an Oppose Unless Amended position on your Assembly Bill 1442. This position was taken at the board's May 1 board meeting, and verbal notice of this position was shared with your office after the meeting.

Assembly Bill 1442 would modify the definition and handling of currently classified medical waste in the California Health and Safety Code. We have concerns with some of its provisions.

First, we believe that AB 1442 would introduce ambiguity and/or conflict into the Health and Safety Code, because pharmaceuticals, which are "biohazardous waste" under existing Health and Safety Code section 117635, and "medical waste" (when dispensed for diagnosis or treatment) under existing Health and Safety Code section 117690, are now being cross-designated in proposed section 117748 as "pharmaceutical waste." Is pharmaceutical waste still a sub-category of medical waste, or is it now a totally separate category? We are confused about a whole new category of "pharmaceutical waste" without referencing sections 117635 and 117690, and clarifying its relationship to "medical waste." We are confused about creating a whole new category.

We are also not clear about whether AB 1442's proposed section 117748(b) would remove certain types of pharmaceutical waste from what would be classified as pharmaceutical waste in section 117748(a). How would such waste then be classified?

As you know, the Board of Pharmacy regulates reverse distributors as a type of drug wholesaler that under Business and Professions Code section 4040.5 specifically handle drugs that are being removed from commerce and California's pharmaceutical supply. This Business and Professions Code section provides that a reverse distributor acts by " . . . receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs."

However, as proposed in 117748(b), if a generator makes the decision that a nonsalable drug has "potential value to the generator" because the nonsalable drug is being returned to a reverse distributor (that must also be a licensed transfer station) "for possible manufacturer credit," is the drug is exempted from being classified as pharmaceutical waste? If so, is it therefore exempted from being classified as medical waste? Thus the classification and

handling of outdated and nonsalable drugs that are being removed from commerce for destruction will be based on whether the generator believes the drugs have potential for a manufacturer credit.

The board also has concerns about the codification of the phrase "potential value to the generator" being used to apply to a nonsalable drug. We see no need for California law to specifically classify that nonsalable drugs (that are nonsalable because they are expired, adulterated or contaminated) have any value when – by definition – they cannot be sold or administered to patients, and are being removed from commerce for destruction.

We believe that other sections of the bill also need amendment to provide clarity. For example, in section 7 of the bill to add section 118032, there is no definition of what a "pharmaceutical waste hauling exemption" is, nor what exemption it creates.

We also respectfully request amendment to all sections referencing a common carrier for transport to require that notification be provided to the generator when the pharmaceutical waste arrives at its destination. Without this requirement, pharmaceutical waste can be provided to a common carrier that never arrives at its destination. This theft /loss would go undetected. This is a potential for drug diversion by the common carrier and possibly the receiving agency. Additionally, a requirement should be placed on the generator to file a loss report with the enforcement agency if such notification is not received within a specific period of time (e.g., 72 hours).

The generator needs to record what it is shipping in some form (type of drugs, quantity, weight). Without such documentation, there is no way to identify that drugs are missing upon receipt by the waste hauler or reverse distributor. Without such record keeping by the generator, there is no way to identify what drugs may be diverted by staff with access to the waste, the common carrier that transports the waste, and perhaps even the destruction agency. Again, discrepancies should require notification to the enforcement agency within a specified period of time.

We also request amendments to specify that a generator that does not separate pharmaceutical from other medical waste, results in the commingled waste being classified and handled only as medical waste.

Thank you for this opportunity to provide comments on AB 1442. We will be happy to meet with you to clarify our proposed amendments and work on resolutions. Additionally, please do not hesitate to contact me (574-7911) if you have questions.

Sincerely,

VIRGINIA HEROLD
Executive Officer

cc: Department of Consumer Affairs

BILL NUMBER: AB 2348 AMENDED
BILL TEXT

AMENDED IN SENATE JUNE 20, 2012
AMENDED IN ASSEMBLY MAY 29, 2012
AMENDED IN ASSEMBLY MARCH 29, 2012

INTRODUCED BY Assembly Member Mitchell
(Principal coauthors: Assembly Members Atkins, Butler, and Chesbro)
(Coauthor: Assembly Member Ma)
(Coauthor: Senator De León)

FEBRUARY 24, 2012

An act to amend Section 2725.1 of, and to add Section 2725.2 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2348, as amended, Mitchell. Registered nurses: dispensation of drugs.

Existing law, the Nursing Practice Act, authorizes a registered nurse to dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a specified clinic.

This bill would, in addition, authorize a registered nurse to dispense specified drugs or devices upon an order issued by a certified nurse-midwife, nurse practitioner, or physician assistant if the nurse is functioning within a specified clinic. The bill would also authorize a registered nurse to dispense or administer hormonal contraceptives in strict adherence to specified standardized procedures, if the nurse is functioning within a specified clinic.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 2725.1 of the Business and Professions Code is amended to read:

2725.1. *(a)* Notwithstanding any other provision of law, a registered nurse may dispense drugs or devices upon an order by a licensed physician and surgeon *or an order by a certified nurse-midwife, nurse practitioner, or physician assistant issued pursuant to Section 2746.51, 2836.1, or 3502.1, respectively,* if the *registered* nurse is functioning within a licensed *primary care* clinic as defined in ~~paragraphs (1) and (2) of~~ subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b) *, (c) , (h),* or ~~(c)~~ *(j)* of Section ~~1206,~~ *1206* ~~of~~ *of,* the Health and Safety Code.

(b) No clinic shall employ a registered nurse to perform dispensing duties exclusively. No registered nurse shall dispense drugs in a pharmacy, keep a pharmacy, open shop, or drugstore for the retailing of drugs or poisons. No registered nurse shall compound drugs. Dispensing of drugs by a registered nurse, except a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51 or a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, shall not include substances included in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code). Nothing in this section shall exempt a clinic from the provisions of Article 13 (commencing with Section 4180) of Chapter 9.

(c) Nothing in this section shall be construed to limit any other authority granted to a certified nurse-midwife pursuant to Article 2.5 (commencing with Section 2746), to a nurse

practitioner pursuant to Article 8 (commencing with Section 2834), or to a physician assistant pursuant to Chapter 7.7 (commencing with Section 3500).

SEC. 2. Section 2725.2 is added to the Business and Professions Code, to read:

2725.2. (a) Notwithstanding any other provision of law, a registered nurse may dispense self-administered hormonal contraceptives approved by the federal Food and Drug Administration (FDA) and may administer injections of hormonal contraceptives approved by the FDA in strict adherence to standardized procedures developed in compliance with subdivision (c) of Section 2725 if the nurse is functioning within a licensed primary care clinic as defined in subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b), (c), (h) , or (j) of Section 1206 of, the Health and Safety Code.

(b) The standardized procedure described in subdivision (a) shall specify all of the following:

(1) Which nurse may dispense or administer the hormonal contraceptives.

(2) Which hormonal contraceptives may be dispensed or administered under specified circumstances, utilizing the most recent version of the United States Medical Eligibility Criteria for Contraceptive Use.

(3) The extent of physician and surgeon supervision required.

(4) The method of periodic review of the nurse's competence.

(5) The method of periodic review of the standardized procedure, including, but not limited to, the required frequency of review and the person conducting that review.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER:	**AB 2348**	**VERSION:**	**Amended June 20, 2012**
AUTHOR:	**Mitchell**	**SPONSORS:**	**Planned Parenthood Affiliates of Ca.** **California Family Health Council**

BOARD POSITION: None

SUBJECT: **Registered nurses: dispensation of drugs**

Affected Sections: An act to amend Section 2725.1 of the Business and Professions Code, relating to healing arts.

Current Status: Do pass in Assembly Business Professions and Economic Development Committee and re-referred to the Committee on Rules

Recent Update:

On May 1, 2012, the Board took a "Watch" position. Since that time, the bill has been amended to specify the standardized procedure / protocol under which a Registered Nurse may dispense self-administered hormonal contraceptives and also administer injections of hormonal contraceptives, and makes other changes specific to the Nursing Practice Act.

EXISTING LAW:

1. Provides for the scope of practice of a Registered Nurse under the authority of the Nursing Practice Act, administered by the Board of Registered Nursing (Business and Professions Code Section 2700 et seq.).
2. A registered nurse is authorized to dispense drugs or devices in a clinic licensed pursuant to Sections 1204 or 1206, as specified. With limited exceptions, a nurse shall not dispense controlled substances. (Business and Professions Code Section 2725.1)
3. Specifies various clinic settings in the Health and Safety Code.

THIS BILL WOULD:

1. Specify that in a clinic licensed pursuant to Section 1204(a) or Section 1206(b) or (c) a nurse may dispense drugs or devices upon an order by a licensed physician and surgeon *or on order issued by a certified nurse-midwife, nurse practitioner, or physician assistant*, as specified.
2. Specify that a registered nurse may dispense hormonal contraceptives in a primary care clinic (defined at Section 1204(a) of the Health and Safety Code) or in a clinic (defined at

Section 1206 (b) (c) or (h) of the Health and Safety Code pursuant to an established protocol.

AUTHOR'S INTENT:
According to the author, utilizing a standardized procedure (protocol) would allow a Registered Nurse with the ability to provide hormonal contraceptives to patients after the RN conducts a patient assessment pursuant to approved medical guidelines. This includes reviewing basic health indicators like age and blood pressure, and analyzing the patient's health history. Further, the author states that AB 2348 will expand access to birth control by allowing RNs to dispense these drugs under a protocol, thereby helping to meet the needs of women.

COMMENTS:
Information obtained from the Board of Registered indicates that a registered nurse would be able to perform these duties if deemed clinically competent to do so by the supervising physician, nurse practitioner, certified nurse-midwife or physician assistant.

BILL NUMBER: SB 419 INTRODUCED
BILL TEXT

INTRODUCED BY Senator Simitian

FEBRUARY 16, 2011

An act to amend Sections 47115 and 47116 of the Public Resources Code, relating to solid waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 419, as introduced, Simitian. Solid waste: home-generated sharps.

Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices. The manufacturer is required to post and maintain a copy of the plan on its Internet Web site.

This bill would require the above plan to be submitted in an electronic format as prescribed by the department. The bill would require the manufacturer to post and maintain a copy of the plan in a readily accessible location on its Internet Web site.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 47115 of the Public Resources Code is amended to read:

47115.

A pharmaceutical manufacturer that sells or distributes a medication in California that is usually intended to be self-injected at home through the use of a hypodermic needle, pen needle, intravenous needle, or any other similar device, shall, on or before July 1, 2010, and annually thereafter, submit to the ~~board, or its successor agency~~*department*, a plan that describes how the manufacturer supports the safe collection and proper disposal of the waste devices. *The plan shall be submitted in an electronic format as prescribed by the department*.

SEC. 2. Section 47116 of the Public Resources Code is amended to read:

47116.

(a) The manufacturer shall post and maintain a copy of the plans required pursuant to Section 47115 *in a readily accessible location* on its Internet Web site.

(b) The ~~board, or its successor agency,~~ *department* shall post and maintain copies of the plans submitted by the manufacturers pursuant to Section 47115 on its Internet Web site.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: **SB 419** **VERSION: Introduced February 16, 2011**

AUTHOR: **Simitian** **SPONSOR:**

SUBJECT: **Solid Waste: Home-Generated Sharps**

BOARD POSITION: None

Affected Sections: Amend Sections 47115 and 47116 of the Public Resources Code related to solid waste.

Current Status: On the Assembly Inactive File (6/20/12)

COMMENTS:
As recently as June 20, 2012, staff has been in touch with the author's office. According to the Senator's staff, the Senator considers the bill active – though on the Inactive File. Amendments are likely towards the end of the session, but no amendments have been shared with the board.

EXISTING LAW:
Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources and Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices. The manufacturer is required to post and maintain a copy of the plan on its Internet Web site.

THIS BILL:
Would require that a pharmaceutical manufacturer to submit the required report in an electronic format, and that the plan be in a readily accessible location on its Internet Web site.

FISCAL/ECONOMIC IMPACT:
No fiscal impact, as introduced.

BILL NUMBER: SB 1301 AMENDED
BILL TEXT

AMENDED IN SENATE MAY 1, 2012
AMENDED IN SENATE APRIL 16, 2012
AMENDED IN SENATE MARCH 29, 2012

INTRODUCED BY Senator Hernandez
(Principal coauthor: Assembly Member Mitchell)
(Coauthor: Senator Emmerson)

FEBRUARY 23, 2012

An act to add Section 4064.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1301, as amended, Hernandez. Prescription drugs: 90-day supply.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy. Existing law prohibits a person from furnishing a dangerous drug except upon the prescription of specified practitioners, except as specified. Existing law authorizes a pharmacist filling a prescription order for a drug product to substitute a generic drug product or a drug product with a different form of medication having the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product, subject to specified requirements. Existing law also authorizes a pharmacist to refill a prescription for a dangerous drug without the prescriber's authorization under specified circumstances.

This bill would authorize a pharmacist, if the patient has completed an initial 30-day supply of a dangerous drug, to dispense not more than a 90-day supply of that dangerous drug other than a controlled substance pursuant to a valid prescription if the pharmacist is exercising his or her professional judgment, he or she dispenses no more than the total amount prescribed, including refills, and the prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary. *The bill would prohibit a pharmacist from dispensing a dang erous drug pursuant to these provisions if the prescriber personally indicates "Dispense as written" or words of similar meaning.* The bill would require a pharmacist dispensing a dangerous drug pursuant to these provisions to notify the prescriber of the change in the quantity of dosage units dispensed. The bill would provide that these provisions are not applicable to psychotropic medication or psychotropic drugs, as described.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4064.5 is added to the Business and Professions Code, to read:

4064.5.

(a) A pharmacist may dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies the initial dispensing of a lesser amount followed by periodic refills of that amount if the patient has completed an initial 30-day supply of the dangerous drug and all of the following requirements are satisfied:

(1) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.

(2) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

(3) The pharmacist is exercising his or her professional judgment.

(b) A pharmacist dispensing a dangerous drug pursuant to this section shall notify the prescriber of the change in the quantity of dosage units dispensed.

(c) In no case shall a pharmacist dispense a greater supply of a dangerous drug pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Dispense as written," or words of similar meaning.

(d) This section shall not apply to psychotropic medication or psychotropic drugs as described in subdivision (d) of Section 369.5 of the Welfare and Institutions Code.

(e) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a dangerous drug in a manner inconsistent with a beneficiary's plan benefit.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NO.:	**SB 1301**	**VERSION:**	**A – May 1, 2012**
AUTHOR:	**Hernandez** **Coauthors: Mitchell and Emmerson**		
SUBJECT:	**Prescription Drugs: 90-Day Supply**		
BOARD POSITION:	**Support (Ver. 4/16/12)**		

Affected Sections: Add Section 4064.5 to the Business and Professions Code.

CURRENT STATUS:
June 26, 2012 – Set for Hearing in Assembly Health

RECENT AMENDMENTS:
The Board established a position of Support on May 1. Since that time, the bill was amended to specify that a pharmacist shall not dispense a greater supply of a dangerous drug in accordance with the section, if the prescriber indicates "dispense as written" or words of similar meaning.

STAFF RECOMMENDATION:
Continue to Support

EXISTING LAW:
1. B&PC § 4024 defines "Dispense" as the furnishing of drugs or devices upon a prescription from an authorized prescriber, and also refers to the furnishing of drugs or devices directly to a patient by a prescriber, as specified.
2. B&PC § 4063 specifies "No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed."
3. B&PC § 4064 provides for the emergency refilling of a prescription without prescriber authorization.
4. 16 CCR Section 1716 precludes a pharmacist from deviating from the requirements of a prescription, except upon consent of the prescriber, or to select another drug product in accordance with B&PC § 4063.

THIS BILL WOULD:
1. Add Section 4064.5 to the Business and Professions Code to specify limited circumstances by which a pharmacist may dispense not more than a 90-day supply of a dangerous drug (not a controlled substance) pursuant to a valid prescription for a lesser amount, with refills (such as 30-day supply), so long as specified requirements are met:

- The patient has completed an initial 30-day supply of the drug, AND all of the following requirements are met:
    i. The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.
    ii. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary; and
    iii. The pharmacist is exercising his or her professional judgment.
- The pharmacist notifies the prescriber of the change in the quantity of dosage units dispensed.
- The provisions would not apply to psychotropic medication or psychotropic drugs, as specified.
- Preclude a pharmacist from dispensing an amount greater than the prescription is written for if the prescription indicates "dispense as written" or words of similar meaning.

AUTHOR'S INTENT:
According to the author, SB 1301 would permit a pharmacist to dispense a refill prescription drug in a 90-day supply, unless the prescriber indicates otherwise on the prescription document. This could save a patient time and money and would aid in a patient's adherence to a prescribed medication therapy.

COMMENTS:

Under current law, a pharmacist may dispense a 90-day supply of a dangerous drug (other than a controlled substance) pursuant to a valid prescription for a lesser amount, so long as the pharmacist receives authorization from the prescriber. This measure would establish limited conditions by which a pharmacist can dispense a 90-day supply after the patient has completed a 30-day supply of that drug, and provided the pharmacist notifies the prescriber of the change in dosage units dispensed.

However, the board's regulation at 16 CCR 1716 specifies that a pharmacist **shall not** deviate from the requirements of a prescription, except as specified. If enacted, the board's regulation may require amendment so as to not conflict with the provisions of the bill.

SB 1301 is silent as to patient interaction. Thus, a pharmacist, complying with the provisions of the bill, would be able to dispense a 90-day supply of a prescription drug without knowing if the patient ***wants*** a 90-day supply. Board staff believes there should be some level of interaction with the patient to determine if the patient wants an amount greater than what the prescription is written for.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 24, 2012

The Honorable Ed Hernandez, O.D.
Member, California State Senate
State Capitol, Room 4085
Sacramento, CA 95816

RE: Senate Bill 1301 - Support

Dear Senator Hernandez:

I am pleased to advise you that on May 1, 2012, the Board of Pharmacy took a ***Support*** position on your measure, SB 1301, which would permit a pharmacist to dispense a 90-day supply of a dangerous drug other than a controlled substance, pursuant to a valid prescription, as specified.

The practice of pharmacy is a dynamic profession – one in which licensed, highly qualified professionals exercise professional judgment, and work to meet the needs of the patient. Senate Bill 1301 specifies criteria by which a pharmacist can fill a 90-day supply of a prescription medication without having first to contact the physician. This saves the patient and the physician time. Also, by having a 90-day supply of a medication, a patient is more likely to adhere to his or her medication therapy.

If you have any questions, please do not hesitate to contact me at (916) 574-7911.

Sincerely,

VIRGINIA HEROLD
Executive Officer

cc: Department of Consumer Affairs

BILL NUMBER: SB 1329 AMENDED
BILL TEXT

AMENDED IN SENATE MAY 14, 2012
AMENDED IN SENATE MARCH 29, 2012

INTRODUCED BY Senator Simitian
(Coauthor: Assembly Member Galgiani)

FEBRUARY 23, 2012

An act to amend Sections 150201, 150202, 150204, and 150205 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 1329, as amended, Simitian. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which a pharmacy that is owned by or contracts with the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law requires a county that has established a program to establish procedures to, among other things, ensure proper safety and management of any medications collected and maintained by a participating pharmacy. Existing law authorizes a skilled nursing facility, specified drug manufacturer, or pharmacy wholesaler to donate medications to the program. Existing law requires medication under the program to be dispensed to an eligible patient, destroyed, or returned to a reverse distributor, as specified. Except in cases of noncompliance, bad faith, or gross negligence, existing law prohibits certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program's provisions.

This bill would authorize a county to establish the program by action of the county board of supervisors or by action of a public health officer of the county, as prescribed. This bill would also authorize specified primary care clinics and pharmacies to participate in the program. This bill would require a pharmacy or clinic seeking to participate in the program to inform the county health department in writing of its intent and prohibit the pharmacy or clinic from participating until the county health department has confirmed that it has received this notice. This bill would require participating pharmacies and clinics to disclose specified information to the county health department and require the county board of supervisors or public health officer to make this information available upon request to the California State Board of Pharmacy. This bill would authorize the county board of supervisors, public health officer, and California State Board of Pharmacy to prohibit a pharmacy or clinic from participating in the program, under certain circumstances. This bill would authorize licensed health and care facilities, as specified, to donate unused medications to the program. This bill would also make other conforming changes to those provisions.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 150201 of the Health and Safety Code is amended to read:

150201.

For purposes of this ~~division, "medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.~~ *division:*

(a) "Eligible entity" means all of the following:

(1) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is county owned or that contracts with the county pursuant to this division.

(2) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and operated by a licensed primary care clinic, as defined in Section 1204.

(3) A licensed primary care clinic, as defined in Section 1204, that is licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code.

(b) "Medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.

(c) "Participating entity" means an eligible entity that has received written or electronic documentation from the county health department pursuant to paragraph (3) of subdivision (a) of Section 150204 and that operates a repository and distribution program pursuant to this division.

SEC. 2. Section 150202 of the Health and Safety Code is amended to read:

150202.

Notwithstanding any other provision of law, ~~a licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease, may donate unused medications under a program established pursuant to this division.~~

the following health and care facilities may donate unused medications under a program established pursuant to this division:

(a) A licensed general acute care hospital, as defined in Section 1250.

(b) A licensed acute psychiatric hospital, as defined in Section 1250.

(c) A licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease.

(d) A licensed intermediate care facility, as defined in Section 1250.

(e) A licensed intermediate care facility/developmentally disabled-habilitative facility, as defined in Section 1250.

(f) A licensed intermediate care facility/developmentally disabled-nursing facility, as defined in Section 1250.

(g) A licensed correctional treatment center, as defined in Section 1250.

(h) A licensed psychiatric health facility, as defined in Section 1250.2.

(i) A licensed chemical dependency recovery hospital, as defined in Section 1250.3.

(j) A licensed residential care facility for the elderly, as defined in Section 1569.2.

(k) A licensed residential care facility for persons with chronic, life-threatening illness, as defined in Section 1568.01.

(l) An approved mental health rehabilitation center, as described in Section 5675 of the Welfare and Institutions Code.

SEC. 3. Section 150204 of the Health and Safety Code is amended to read:

150204.

(a) *(1)* A county may establish, by ~~ordinance, a repository and distribution program for purposes of this division. Only pharmacies that are county-owned or that contract with the county pursuant to this division~~ *an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division.*

(2) Only an eligible entity, pursuant to subdivision (a) of Section 150201,

may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in paragraph (3) of subdivision (a) of Section 150201 shall disclose to the county health department the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this paragraph.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division.

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b) A county that elects to establish a repository and distribution program pursuant to this division shall establish procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a ~~county-owned or county-contracted, licensed pharmacy~~*participating entity*.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a ~~skilled nursing facility, shall have been under the control of staff of the skilled nursing facility~~*health or care facility, as described in Section 150202, shall have been under the control of staff of the health or care facility, as described in Section 150202*.

(d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program.

(e) A pharmacist *or physician* shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist *or physician* shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in ~~any of~~ the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor.

(4) Transferred to another participating entity to be dispensed to eligible patients pursuant to this division.

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h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed *or transferred* under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) Medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(j) Medication donated to the repository and distribution program shall be segregated from the ~~pharmacy's~~ *participating entity's* other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) ~~The pharmacy~~ *A participating entity* shall keep complete records of the acquisition and disposition of medication donated ~~to~~ *to, and transferred* and dispensed ~~under~~ *under,* the repository and distribution program. These records shall be kept separate from the ~~pharmacy's~~ *participating entity's* other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

~~(l)~~ *(l)* Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health ~~and~~ Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, *shall* include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at ~~their~~ appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating ~~county-owned or county-contracted pharmacy~~ *entity* shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

SEC. 4. Section 150205 of the Health and Safety Code is amended to read:
150205.

The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:

(a) A prescription drug manufacturer, wholesaler, governmental entity, ~~county-owned or county-contracted licensed pharmacy, or skilled nursing facility~~*or participating entity*.

(b) A pharmacist or health care professional who accepts or dispenses prescription drugs.

(c) A health or care facility, as described in Section 150202.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NO.:	**SB 1329**	**VERSION:**	**Amended 5/14/12**
AUTHOR:	**Simitian**		
SUBJECT:	**Surplus Medication Collection and Distribution**		
Board Position:	**Support if Amended (Ver 3/29/12)**		

Affected Sections: Health & Safety Code Sections **150201, 150202, 150204** and **150205** Division 116. Surplus Medication Collection and Distribution (§§ 150200-150207)

BILL STATUS:
5/25/12 – Referred to ASM Committee on Health

RECENT UPDATES:
At the May 2012 Board Meeting, the board established a position of Support if Amended (for the March 29, 2012 version). Since that time, staff has worked with the Senator's office to address the board's concerns. The current version of the bill contain amendments that address some of the board's concerns, but there are a few areas that remain outstanding, Staff is continuing to work with the author's office on those issues.

STAFF RECOMMENDATION:
Maintain board's position of Support if Amended.

EXISTING LAW:
Under existing [1]law, a county may voluntarily establish a Surplus Medication Collection and Distribution (SMCD) Program through a county-owned pharmacy or a pharmacy that contracts with the county for this purpose. Counties that elect to operate a program by ordinance of the County Board of Supervisors must establish criteria to determine who is eligible to receive drugs from the program; develop a formulary of medications appropriate for the program; ensure the privacy of individuals for whom the medication was originally prescribed; and ensure the safe storage and management of medications that are collected and dispensed under the program. No controlled drugs may be donated, and a pharmacist or physician and surgeon must dispense the medications to eligible patients.

Existing Pharmacy Law provides for the licensure and regulation of pharmacies, pharmacists, wholesalers of dangerous drugs or devices, and other individuals and entities.

THIS BILL WOULD:
- Also allow a county Public Health Officer to establish a Surplus Medication Collection and Distribution Program in a county.

[1] Division 116 of the Health and Safety Code, Sections 150200-150207

- Expand the types of facilities/entities that may donate surplus medications to a SMCD Program, to include [2]residential care facilities and [3]mental health rehabilitation centers.
- Allow for the transfer of donated surplus medications between SMCD programs.
- Require that eligible programs disclose specified information to the county and that, upon request, make that information available to the board.
- Allow a physician to determine if donated medications meet specified standards, and to adhere to standard pharmacy practices when dispensing medications.
- Authorize the Board of Pharmacy to prohibit an entity from participating in a SMCD program.

FOR DISCUSSION:

Patient Drugs – This measure is silent on the patient's ownership of their drugs.

Donating Facilities [SEC. 2, H&SC 150202] – Staff are addressing the bill's provisions that allow Residential Care Facilities for the Elderly to donate unused Medications.

Board Authority – The author has agreed to amendments that would require eligible entities to notify the board of their intent to participate in the program (in addition to notifying the county of that intent), notify the board of the entity's participating, and to submit records on a quarterly basis.

Drug Storage & Transfer – Current law requires that donated drugs must be kept physically separate from a pharmacy's or clinic's other drug supply.

This bill allows for the permissive transfer of donated drugs from one approved program to another. According to the author, this would allow donated drugs to be directed where they are needed most. The bill specifies there shall be "complete records of the acquisition and disposition" of donated drugs. It is unclear what 'complete records' shall include. Likewise, SB 1329 is silent on how drugs transfers are to be made. Staff continue to address the "transfer" of donated drugs.

Physician Oversight – The author has agreed to amendments that would specify that the physician responsible at a clinic, would be the professional director that is on file with the Board for the clinic license.

Drug Disposal – Staff continue to address with the author provisions regarding the destruction or transportation of donated medications that are not eligible for redistribution.

[2] Licensed by the Department of Social Services
[3] Licensed by the Department of Mental Health, Welfare and Institutions Code § 5675

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 17, 2012

The Honorable Joe Simitian
Member, California State Senate
State Capitol, Room 2080
Sacramento, CA 95816

RE: Senate Bill 1329

Dear Senator Simitian:

I am writing to formally advise you that the Board of Pharmacy took a Support if Amended position on your SB 1329 at the Board Meeting held May 1, 2012.

Senate Bill 1329 would expand drug redistribution and repository programs in California to offer wider participation and drug donation options, with the intent to expand delivery of prescription medication to medically indigent patients, medication that could otherwise be destroyed. The board commends the use of such programs and your efforts to create such options.

Prescription drug abuse is now a widespread concern in the US. In 2009, prescription drug abuse killed more individuals than did automobile accidents. The board's interests and suggested amendments to SB 1329 are intended to ensure that drug diversion opportunities are not created inadvertently. Previously dispensed drugs donated to the county programs are not subject to the normal controls built into the distribution requirements for prescription medication.
Some of the medications redistributed in such programs are very costly to purchase, so preventing opportunities where these drugs could be illegally resold back into the supply chain is a board goal. Much board enforcement activity takes place to ensure the quality of medication dispensed to patients in California, and to prevent, and detect and prosecute diversion and fraud.

We have suggested a number of small amendments to the current version of SB 1329. For ease of review, I have placed them into a mocked-up version of the bill, enclosed. If it would be easier for you and your staff to review them in a different manner, please let me know and I will convert them into your preferred format.

Please do not hesitate to contact me (574-7911) if I can be of assistance in any way or clarify these suggestions.

Thank you for your consideration of these suggested amendments.

Sincerely,

VIRGINIA HEROLD
Executive Officer

Enclosure
cc: Department of Consumer Affairs

AMENDED IN SENATE MAY 14, 2012
AMENDED IN SENATE MARCH 29, 2012

SENATE BILL No. 1329

Introduced by Senator Simitian
(Coauthor: Assembly Member Galgiani)
February 23, 2012

An act to amend Sections 150201, 150202, 150204, and 150205 of the Health and Safety Code, relating to pharmaceuticals.

SB 1329, as amended, Simitian. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which a pharmacy that is owned by or contracts with the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law requires a county that has established a program to establish procedures to, among other things, ensure proper safety and management of any medications collected and maintained by a participating pharmacy. Existing law authorizes a skilled nursing facility, specified drug manufacturer, or pharmacy wholesaler to donate medications to the program. Existing law requires medication under the program to be dispensed to an eligible patient, destroyed, or returned to a reverse distributor, as specified. Except in cases of noncompliance, bad faith, or gross negligence, existing law prohibits certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program's provisions.

This bill would authorize a county to establish the program by action of the county board of supervisors or by action of a public health officer of the county, as prescribed. This bill would also authorize specified primary care clinics and pharmacies to participate in the program. This bill would require a pharmacy or clinic seeking to participate in the program to inform the county health department in writing of its intent and prohibit the pharmacy or clinic from participating until the county health department has confirmed that it has received this notice. This bill would require participating pharmacies and clinics to disclose specified information to the county health department and require the county board of supervisors or public health officer to make this information available upon request to the California State Board of Pharmacy. This bill would authorize the county board of supervisors, public health officer, and California State Board of Pharmacy to prohibit a pharmacy or clinic from participating in the program, under certain circumstances. This bill would authorize licensed health and care

facilities, as specified, to donate unused medications to the program. This bill would also make other conforming changes to those provisions.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

SECTION 1. Section 150201 of the Health and Safety Code is amended to read:

150201. For purposes of this division:

(a) "Eligible entity" means all of the following:

(1) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is county owned or that contracts with the county pursuant to this division. The pharmacy shall not be on probation with the California State Board of Pharmacy.

(2) ~~A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and operated by a licensed primary care clinic, as defined in Section 1204.~~

~~(3)~~ A licensed primary care clinic, as defined in Section 1204, that is licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code. The clinic shall not be on probation with the California State Board of Pharmacy.

(b) "Medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code. Medication or medications does not include any substances listed in Chapter 2 (commencing with section 111053) of Division 10 of the Health and Safety Code.

(c) "Participating entity" means an eligible entity that has received written or electronic documentation from the county health department pursuant to paragraph (3) of subdivision (a) of Section 150204 and that operates a repository and distribution program pursuant to this division.

SEC. 2. Section 150202 of the Health and Safety Code is amended to read:

150202. Notwithstanding any other provision of law, the following California-licensed health and care facilities may donate with the patient's consent unused medications under a program established pursuant to this division, provided the medication has never been in the control or possession of the patient or:

(a) A licensed general acute care hospital, as defined in Section 1250.

(b) A licensed acute psychiatric hospital, as defined in Section 1250.

(c) A licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease.

(d) A licensed intermediate care facility, as defined in Section 1250.

(e) A licensed intermediate care facility/developmentally disabled-habilitative facility, as defined in Section 1250.

(f) A licensed intermediate care facility/developmentally disabled-nursing facility, as defined in Section 1250.

(g) A licensed correctional treatment center, as defined in Section 1250.

(h) A licensed psychiatric health facility, as defined in Section 1250.2.

(i) A licensed chemical dependency recovery hospital, as defined in Section 1250.3.

~~(j) A licensed residential care facility for the elderly, as defined in Section 1569.2.~~

~~(k) A licensed residential care facility for persons with chronic, life-threatening illness, as defined in Section 1568.01.~~

(*l*) An approved mental health rehabilitation center, as described in Section 5675 of the Welfare and Institutions Code.

SEC. 3. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days after establishing a repository and distribution program.

(2) Only an eligible entity, pursuant to subdivision (a) of Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent. The county shall within 30 days notify the California State Board of Pharmacy in writing of all notices of intent received by the county.

(4) (A) A participating entity shall disclose to the county health department the name and location of the source of all donated medication it receives on a quarterly basis.

(B) A participating primary care clinic, as described in paragraph (2)

~~(3)~~ of subdivision (a) of Section 150201 shall disclose to the county health department the California licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director as specified in section 4182(c) of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this ~~paragraph~~.division.

(5) The county board of supervisors, the public health officer of the county, ~~and~~ or the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. Written notice shall be provided to any eligible or participating entity that is prohibited from participating in the program within 15 days of such a determination. The county board of supervisors, the public health office or the California State Board of Pharmacy shall ensure that all these agencies receive the prohibition notice that has been provided to the eligible or participating entity.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in

Section 150202, shall have been under the control of California licensed health care staff of the health or care facility~~, as described in Section 150202~~.

(d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed or provided by the repository and distribution program, and must be immediately provided to a licensed waste hauler for destruction.

(e) A pharmacist or physician at the participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed or transferred under this program and shall be either destroyed or returned to a reverse distributor or license waste hauler. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) Medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(j) Medication donated to the repository and distribution program shall be segregated from the participating entity's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, transferred, ~~*and transferred* and~~ dispensed or destroyed *under,* the repository and

distribution program. These records shall be kept separate from the participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(*l*) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating entity shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

SEC. 4. Section 150205 of the Health and Safety Code is amended to read:

150205. The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:

(a) A prescription drug manufacturer, wholesaler, governmental entity, or participating entity.

(b) A pharmacist or ~~health care professional~~ physician who accepts or dispenses prescription drugs.

(c) A health or care facility, as described in Section 150202.

Agenda Item A.2

Legislation Report

b. Sunset Review and Legislative Oversight

BILL NUMBER: SB 1237 AMENDED
BILL TEXT

AMENDED IN ASSEMBLY JUNE 15, 2012
AMENDED IN SENATE APRIL 30, 2012
AMENDED IN SENATE APRIL 16, 2012

INTRODUCED BY Senator Price

FEBRUARY 23, 2012

An act to amend Sections *2006, 2450.3, 2602, 2607.5,* 4001, 4003, 8000, 8005, 8027, 8030.2, and 8030.5 of the Business and Professions Code, *and to amend Section 12529.6 of the Government Code,* relating to professions *and vocations* , and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1237, as amended, Price. Professions *and vocations* : ~~pharmacists, court reporters, and Transcript Reimbursement Fund: sunset dates.~~ *regulatory boards.*

(1) Existing law, until January 1, 2013, declares that using a vertical enforcement and prosecution model for the Medical Board of California's investigations is in the best interests of the people of California. Under existing law, a vertical enforcement and prosecution model is described as the joint assignment a complaint to a board investigator and to a deputy attorney general responsible for prosecuting the case if the investigation results in the filing of an accusation. Existing law requires the board to, among other things, establish and implement a plan to locate specified staff in the same offices in order to carry out the intent of the vertical enforcement and prosecution model.

This bill would extend the operation of these provisions to January 1, 2014 and would also make a conforming change in that regard.

(2) Existing law, the Naturopathic Doctors Act, provides for the licensure and regulation of naturopathic doctors by the Naturopathic Medicine Committee within the Osteopathic Medical Board of California. Existing law repeals these provisions on January 1, 2014. Under existing law, boards scheduled for repeal are required to be evaluated by the Joint Sunset Review Committee.

This bill would make a conforming change with regard to the operation of these provisions until January 1, 2014, and the bill would also specify that this board would be subject to review by the appropriate policy committees of the Legislature.

(3) Existing law, the Physical Therapy Practice Act, provides for the licensure and regulation of physical therapists by the Physical Therapy Board of California. Existing law authorizes the board to appoint an executive officer. Existing law makes these provisions inoperative on July 1, 2013, and repealed on January 1, 2014. Under existing law, boards scheduled for repeal are required to be evaluated by the Joint Sunset Review Committee.

This bill would delete the inoperative date and would instead repeal these provisions on January 1, 2014. The bill would also specify that this board would be subject to review by the appropriate policy committees of the Legislature.

~~(1)~~

(4) Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, pharmacists, pharmacy technicians, wholesalers of dangerous drugs or devices, and others by the California State Board of Pharmacy. Existing law authorizes the board to appoint an executive officer. Under existing law, the board and its authority to appoint an executive officer will be repealed on January 1, 2013. Under existing law, boards scheduled for repeal are required to be evaluated by the Joint Sunset Review Committee.

This bill would extend the operation of the California State Board of Pharmacy and its authority to appoint an executive officer until January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.

~~(2)~~

(5) Existing law provides for the licensure and regulation of court reporters by the Court Reporters Board of California within the Department of Consumer Affairs. Existing law authorizes this board to appoint an executive officer and committees as necessary. Existing law repeals these provisions on January 1, 2013.

This bill would extend the operation of these provisions until January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.

Existing law requires, until January 1, 2013, certain fees and revenues collected by the board to be deposited into the Transcript Reimbursement Fund, to be available to provide reimbursement for the cost of providing shorthand reporting services to low-income litigants in civil cases. Existing law authorizes, until January 1, 2013, low-income persons appearing pro se to apply for funds from the Transcript Reimbursement Fund, subject to specified requirements and limitations. Existing law requires the board, until January 1, 2013, to publicize the availability of the fund to prospective applicants. Existing law requires the unencumbered funds remaining in the Transcript Reimbursement Fund as of January 1, 2013, to be transferred to the Court Reporters' Fund.

This bill would extend the operation of these provisions until January 1, 2017, and would make a technical change to these provisions. By extending the operation of the Transcript Reimbursement Fund, which is a continuously appropriated fund, the bill would make an appropriation.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 2006 of the Business and Professions Code is amended to read:

2006.

(a) Any reference in this chapter to an investigation by the board shall be deemed to refer to a joint investigation conducted by employees of the Department of Justice and the board under the vertical enforcement and prosecution model, as specified in Section 12529.6 of the Government Code.

(b) This section shall remain in effect only until January 1, ~~2013~~*2014*, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2013~~ *2014*, deletes or extends that date.

SEC. 2. Section 2450.3 of the Business and Professions Code is amended to read:

2450.3.

There is within the jurisdiction of the Osteopathic Medical Board of California a Naturopathic Medicine Committee authorized under the Naturopathic Doctors Act (Chapter 8.2 (commencing with Section 3610)). This section shall become inoperative on January 1, ~~2013~~*2014*, and, as of that date is repealed, unless a later enacted statute that is enacted before January 1, ~~2013~~*2014*, deletes or extends that date. ~~The~~ *Notwithstanding any other provision of law, the* repeal of this section renders the Naturopathic Medicine Committee subject to ~~the~~ review ~~required by Division 1.2 (commencing with Section 473)~~*by the appropriate policy committees of the Legislature*.

SEC. 3. Section 2602 of the Business and Professions Code is amended to read:

2602.

The Physical Therapy Board of California, hereafter referred to as the board, shall enforce and administer this chapter~~.~~*.*

This section shall ~~become inoperative on July 1, 2013, and, as of January 1, 2014,~~ *remain in effect only until January 1, 2014, and as of that date* is repealed, unless a later enacted statute, ~~which becomes effective on or~~ *that is enacted* before January 1, 2014, deletes or extends ~~the dates on which it becomes inoperative and is repealed.~~

~~The~~

that date.

Notwithstanding any other provision of law, the

repeal of this section renders the board subject to ~~the~~ review ~~required by Division 1.2 (commencing with Section 473)~~*by the appropriate policy committees of the Legislature*.

SEC. 4. Section 2607.5 of the Business and Professions Code is amended to read:

2607.5.

The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

T

This section shall ~~become inoperative on July 1, 2013, and, as of January 1, 2014,~~ *remain in effect only until January 1, 2014, and as of that date* is repealed, unless a later enacted statute, ~~which becomes effective on or~~ *that is enacted* before January 1, 2014, deletes or extends ~~the dates on which it becomes inoperative and is repealed.~~

~~The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473)~~

that date.

SEC. 5. Section 4001 of the Business and Professions Code is amended to read:

Board of Pharmacy

4001.

(a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) ~~In accordance with Sections 101.1 and 473.1, this~~ *This* section shall remain in effect only until January 1, ~~2013~~*2017*, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2013~~*2017*, deletes or extends that date. ~~The~~ *Notwithstanding any other provision of law, the* repeal of this section renders the board subject to ~~the~~ review ~~required by Division 1.2 (commencing with Section 473)~~*by the appropriate policy committees of the Legislature*.

SEC. 6. Section 4003 of the Business and Professions Code is amended to read:

Board of Pharmacy

4003.

(a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) ~~In accordance with Sections 101.1 and 473.1, this~~ *This* section shall remain in effect only until January 1, ~~2013~~*2017*, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2013~~*2017*, deletes or extends that date.

SEC. 7. Section 8000 of the Business and Professions Code is amended to read:

8000.

(a)

There is in the Department of Consumer Affairs a Court Reporters Board of California, which consists of five members, three of whom shall be public members and two of whom shall be holders of certificates issued under this chapter who have been actively engaged as shorthand reporters within this state for at least five years immediately preceding their appointment.

(b) This section shall remain in effect only until January 1, ~~2013~~*2017*, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2013~~*2017*, deletes or extends that date.

(c) Notwithstanding any other provision of law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 8. Section 8005 of the Business and Professions Code is amended to read:

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NO.: **SB 1237**
Version: **A – June 15, 2012**
Author: **Price**
Subject: **Sunset Review**
Board Position: Support (Version 4/30/12)

Affected Sections: Amend Sections 4001 and 4003 of the Business and Professions Code (B&PC) related to the Board of Pharmacy. The measure also amends various sections of the Business and Professions Code related to other boards and bureaus.

CURRENT STATUS:

6/26/2012 Set for hearing in Assembly Business Professions and Consumer Protection

EXISTING LAW:

1. Business and Professions Code Section 4001 sets forth the structure composure of the Board of Pharmacy, specifies terms of appointment, provides for board member per diem, etc. Existing law "sunsets" the Board of Pharmacy and its authority on January 1, 2013.
2. Business and Professions Code Section 4003 sets forth provisions related to the appointment of an Executive Officer (EO) of the board to include compensation and reimbursement of necessary expenses. This section further specifies duties of the EO related to records and revenue. Existing law "sunsets" these provisions on January 1, 2013.

AS AMENDED THIS BILL WOULD:

1. Amend B&PC Sections 4001 and 4003 to extend the operation of the Board of Pharmacy and its authority to appoint an executive officer until January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.
2. Amend various code sections related to various boards and bureaus. The most recent amendment contains changes relative to the Medical Board of California, the Physical Therapy Practice Act, and the Naturopathic Doctors Act.

   Pharmacy provisions remain unchanged from the April version.

COMMENTS:

In November 2011, the Board provided its "Sunset Review Report 2011" to the Senate Committee on Business, Professions and Economic Development, and also made the report available on the board's public website. The board last underwent sunset review in 2002.
http://www.pharmacy.ca.gov/publications/sunset_2011.pdf

On February 23, 2012, Senator Current Price, Chair of the Senate Committee on Business, Professions and Economic Development introduced SB 1237 to extend the board's authority to 2017. The bill would

also extend the sunset of the Court Reporters Board. On April 16, 2012, the bill was amended to include additional amendments related to the Court Reporters Board Transcript Reimbursement Fund.

The Senate Committee on Business, Professions and Economic Development held an oversight hearing on March 19, 2012, at which Board President Stan Weisser and Executive Officer Virginia (Giny) Herold testified on a variety of issues, including the following topics:

- Effectiveness of the Board's Substance Abuse Recovery Program
- Drug Diversion and Prescription Monitoring Program (CURES)
- E-Pedigree
- Implementation of Patient-Centered Prescription Label Requirements
- Drug Take-Back and reuse Program

BOARD POSITION:

The board established a SUPPORT position at the May 2012 Board Meeting.

STAFF RECOMMENDATION:

Maintain SUPPORT for the June 15th amended version.

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 16, 2012

The Honorable Curren Price
Chair,
Senate Business, Professions and Economic Development Committee
State Capitol, Room 2057
Sacramento, CA 95814

RE: Senate Bill 1237

Dear Senator Price:

On behalf of the California State Board of Pharmacy, thank you for authoring Senate Bill 1237, which would extend the board's sunset date for four years.

The board is grateful for the committee's support over the years for the our consumer protection activities. We look forward to responding to any inquiries members may have about our operations, activities and achievements as this bill moves through the Capitol. We will be in attendance in all legislative committee hearings.

Please do not hesitate to contact me with questions at (916) 574-7911.

Sincerely,

VIRGINIA HEROLD
Executive Officer

Agenda Item A.2

Legislation Report

c. Licensing and Pharmacy Operations

BILL NUMBER: AB 377 AMENDED
BILL TEXT

AMENDED IN ASSEMBLY APRIL 14, 2011

INTRODUCED BY Assembly Member Solorio

FEBRUARY 14, 2011

An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 377, as amended, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant. Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital in either another physical plant on the same premises or on a separate premises, located within a 100-mile radius of the hospital, that is regulated under a hospital's license *, but would impose limitations on the services provided by a centralized hospital pharmacy* . The bill would eliminate the conditions of licensure by the board that limit the services provided by the pharmacy in the other physical plant, but would require that any unit-dose medication produced by a hospital pharmacy under common ownership be barcoded to be readable at the patient's bedside. The bill would authorize a hospital pharmacy to prepare and store a limited quantity of unit-dose medications in advance of a patient-specific prescription under certain circumstances. The bill would also provide that a "manufacturer" does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order. The bill would require a pharmacy compounding or repackaging a drug pursuant to this provision to notify the board of the location of the compounding or repackaging within a specified period of time. Because a knowing violation of the bill's requirements would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4029 of the Business and Professions Code is amended to read:

4029.

(a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a ~~pharmacy~~ *pharmacy, licensed by the board,* that may be located outside of the hospital, in *either* another physical plant ~~that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located. The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant.~~ *on the same premises or on a separate premises, located within a 100-mile radius of the hospital, that is regulated under a hospital's license. A centralized hospital pharmacy may only provide pharmaceutical services to its own patients who are either admitted or registered patients of a hospital within the same health care system.* Nothing in this ~~paragraph~~ *subdivision* shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) Any unit-dose medication produced by a hospital pharmacy under common ownership, as described in Section 4033, shall be barcoded to be readable at the patient's bedside.

(d) A hospital pharmacy may prepare and store a limited quantity of unit-dose medications in advance of receipt of a patient-specific prescription in a quantity as is necessary to ensure continuity of care for an identified population of patients of the hospital based on a documented history of prescriptions for that patient population.

(e) Nothing in this section shall limit the obligation of a hospital pharmacy, hospital, or pharmacist to comply with all applicable federal and state laws.

SEC. 2. Section 4033 of the Business and Professions Code is amended to read:

4033.

(a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding *or repackaging* a drug for parenteral ~~therapy, pursuant to a prescription, for delivery to another pharmacy~~ *therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership* for the purpose of ~~delivering~~ *dispensing* or administering the ~~drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription~~*drug, pursuant to a prescription or order, to the patient or patients named in the prescription or order. A pharmacy compounding or repackaging a drug as described in this paragraph shall notify the board in writing of the location where the compounding or repackaging is being performed within 30 days of initiating the compounding or repackaging. The pharmacy shall report any change in that information to the board in writing within 30 days of the change*.

(3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, "manufacturer" means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer's ~~third-party~~ *third-party* logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

SEC. 3.

No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 377 **VERSION: As Amended April 14, 2011**

AUTHOR: Solorio **SPONSOR: California Hospital Association**

BOARD POSITION: **Support if Amended (May 2011)**

SUBJECT: **Pharmacies: Centralized Hospital Packaging**

AFFECTED SECTIONS: Amend Sections 4029 and 4033 of the Business and Professions Code

CURRENT STATUS: Last location was Assembly Appropriations (6/14/11)

RECENT UPDATES: In recent months, board staff has been working with the author's office on amendments to address the board's concerns. Though not yet in print, amendments are expected which would closely mirror the provisions found in AB 1370 (2009/2010 Session). The board had a position of "Support" for AB 1370. The board's Executive Officer will provide an update on this measure at the June 25th Committee Meeting.

EXISTING LAW:

1. Defines a hospital pharmacy as a pharmacy licensed by the board that is located inside a hospital as specified.
2. Allows a hospital pharmacy to be located outside of the hospital building if the hospital pharmacy is on the California Department of Public Health's consolidated license and if the pharmacy is only providing pharmacy services to inpatients of the hospital.
3. Defines "manufacturer" and exempts compounding, as specified from the definition.

THIS BILL WOULD:

1. Specify a hospital pharmacy may be located outside of a hospital on either the same premises or separate premises, located within 100 mile radius, which is regulated under a hospital's license.
2. Specify that these services can only be provided to its own patients who are either admitted or registered patients of a hospital within the same health care system.
3. Specify that unit-dose medication produced from a centralized pharmacy location for hospitals under common ownership must be barcoded to be readable at the patient's bedside.
4. Allow for anticipatory unit-dose packaging as specified to ensure continuity of patient care.
5. Exempt from the definition of manufacturing, repackaging of a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership for purposes of administering medication pursuant to a prescription order.

6. Require a pharmacy performing such services to notify the board in writing within 30 days of initiating prepackaging or compounding from a centralized location, as well as within 30 days of any change in the information.

AUTHOR'S INTENT:
According to the author, "technology is now capable of providing hospitals with a method to deliver barcoded unit-doses to in-patients' bedsides. However, the cost of this technology renders it virtually impossible for hospitals to do within the structures of the current hospital pharmacy. In addition, because the new central pharmacy would serve multiple hospitals (though the hospitals are under common ownership), currently lawful hospital pharmacy activities might run afoul of the manufacturing law." The author notes that the potential to finally and effectively address in-patient medication errors is greatly expanded by this proposal.

FISCAL IMPACT:
Any minor fiscal impact could be absorbed within existing resources.

COMMENTS:
Recent amendments to this measure clarify that the centralized pharmacy services can only be provided to its own patients who are either admitted or registered patients of a hospital within the same health care system.

This proposal appears consistent with the board's mission statement, "The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement." This proposal would allow a hospital to leverage existing technology to prepare unit-dose medications that include barcoding technology that must be readable at the patient's bedside.

Over the years the board has evaluated the issue of medication errors and reviewed materials and heard presentations from experts on what can be done to reduce such errors. Barcoding technology has been identified as one tool that can be used to reduce medication errors. In 2004, the FDA established bar code label requirements for human drug and biological products (21 CFR Parts 201, 606, et al.) The FDA included in its guidance document, "Bar codes will allow health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. This new system is intended to help reduce the number of medication errors that occur in hospitals and health care settings." (Hospitals are exempt from the FDA requirement to barcode unit-dose packages.) In 2004, the FDA also noted that hospitals that were using bar coding at that time avoided 50% of the adverse drug events caused by errors in the distribution and administration of prescriptions.

A summary from a study published in 2006, "Medication Dispensing Errors and Potential Adverse Drug Events before and after Implementing Bar Code Technology in the Pharmacy, Poon et. Al," included:

> "…our study results suggest that bar code technology in a hospital pharmacy may substantially reduce serious dispensing errors. In particular, it may target several types of dispensing errors that may frequently harm patients, including wrong medication, wrong dose, or wrong formulation errors. However, the scanning technology should be configured to ensure that all doses are scanned at least once during the dispensing process. If optimally configured, this technology may be an important addition to the medication safety armamentarium."

Further, a portion of the discussion from this study also included:

> "The rates of target dispensing errors and potential ADEs substantially decreased after the implementation of bar code technology: The target dispensing error rate decreased by 85%, and the rate of all dispensing-related potential ADEs decreased by more than 60%."

As this measure does not currently specify the requirements of the barcoding, the board may want to consider offering an amendment to clarify what information should be contained within barcode. The board may want to consider the FDA requirement elements established in 21 CFR Parts 201, 606, et al.

PREVIOUS LEGISLATION:

The board previously supported AB 1370 (Solorio, 2009) which contained provisions similar to this bill.

The board previously supported AB 2077 (Solorio, 2010) which contained provisions similar to this bill. This bill was vetoed by the governor.

> "This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California."

BILL NUMBER: AB 1588 AMENDED
BILL TEXT

AMENDED IN ASSEMBLY MARCH 5, 2012

INTRODUCED BY Assembly Member Atkins
(Principal coauthors: Assembly Members Cook and Nielsen)
(Coauthors: Assembly Members Block, Beth Gaines, Pan, V. Manuel Pérez, Williams, and Yamada)

FEBRUARY 6, 2012

An act to add Section 114.3 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 1588, as amended, Atkins. Professions and vocations: reservist licensees: fees and continuing education.

Existing law provides for the regulation of various professions and vocations by boards *, commissions, or bureaus* within the Department of Consumer Affairs and for the licensure *or registration* of individuals in that regard. Existing law authorizes any licensee whose license expired while he or she was on active duty as a member of the California National Guard or the United States Armed Forces to reinstate his or her license without examination or penalty if certain requirements are met.

This bill would require the boards *, commissions, or bureaus* described above to waive the renewal fees and continuing education requirements, if either is applicable, of any licensee *or registrant* who is a reservist called to active duty as a member of the United States Military Reserve or the California National Guard if certain requirements are met.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 114.3 is added to the Business and Professions Code, to read:

114.3.

Notwithstanding any other provision of law, every board, commission, or bureau within the department shall waive the renewal fees and continuing education requirements, if either is applicable, for any licensee or registrant who is a reservist called to active duty as a member of the United States Military Reserve or the California National Guard if all of the following requirements are met:

(a) The licensee or registrant was in good standing with the board, commission, or bureau at the time the reservist was called to active duty.

(b) The renewal fees or continuing education requirements are waived only for the period during which the reservist is on active duty service.

(c) The active duty reservist, or the active duty reservist's spouse or registered domestic partner, provides written notice satisfactory to the board, commission, or bureau that substantiates the reservist's active duty service.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER:	**AB 1588**
VERSION:	**As Amended March 5, 2012 (further amendments expected)**
AUTHOR:	**Atkins**
SUBJECT:	**Professions and Vocations: Reservist licensees: fees and continuing education**

Affected Sections: **Add Section 114.3 to the Business and Professions Code**

CURRENT STATUS: **July 2, 2012 – Set for Hearing in Senate Business Professions and Economic Development**

EXISTING LAW:

1. Pharmacy Law provides that a license, if not renewed, will be cancelled. A cancelled license cannot be renewed.
2. Business and Professions Code Section 114 allows members of the California National Guard or the U.S. Armed Forces to reinstate his or her professional license or registration without examination or penalty if their license expired while the licensee or registrant was on active duty.

AS INTRODUCED, THIS BILL WOULD:

Applies to military reservists called to active duty.

Requires the board to waive a licensee's renewal fee and continuing education requirements, if applicable, for any licensee who is a reservist called to active duty as a member of the U.S. Military Reserve or the California National Guard, provided

- The licensee was in good standing at the time the reservist was called to active duty;
- The renewal fee or C.E. requirements are waived only for the period during which the reservist is on active duty; and
- The reservist, or the active duty reservist's spouse or registered domestic partner, provides written notice satisfactory to the board that substantiates the reservist's active duty service.

In response to concerns expressed by other boards, the author has prepared amendments that would specify that a reservist cannot engage in the activity for which he or she is licensed while his or her license is waived. Expected amendments would also specify that a licensee – when reactivating a waived license – would be required to meet all conditions for licensure renewal, including payment of the renewal fee and continuing education, if applicable.

In addition, the bill will authorize a board to promulgate regulations to implement the provisions of the bill.

AUTHOR'S INTENT:
The author's intent is to establish a provision that would allow a licensee to waive licensure renewal for the period of time when the reservist is called to active duty, and to ensure that military professionals will not be penalized by having his or her license fall into delinquency while called to active duty.

FISCAL IMPACT:
No fiscal impact is anticipated. Any such impact to the processing of renewal licenses would be absorbed with the board's existing staff resources.

COMMENTS:
Board staff anticipates that the two primary license types would be impacted - - pharmacist and pharmacy technician.

RELATED LEGISLATION:
AB 1940 would add Section 115.5 to the Business and Professions Code to require a board to expedite the license application of a spouse of an active military, and would authorize the board the promulgate regulations to implement the provisions of the bill. The board established a Support position on the introduced version of AB 1940.

STAFF RECOMMENDATION
Support

Assemblymember Toni Atkins, 76th Assembly District

AB 1588 – Financial Relief for Military Professionals

IN BRIEF

AB 1588 would provide waivers from professional license renewal fees and continuing education requirements for military reservists called to active duty.

This bill would assure their professional license would remain in good-standing during their service period.

BACKGROUND

The Department of Consumer Affairs is responsible for licensing and overseeing many different professions including automotive, healthcare, security professionals, and others.

Military and Veterans Code § 825 allows annual State Bar membership fees to be waived during a service member's period of military service.

Business and Professions Code § 114 allows members of the California National Guard or the United States Armed Forces to reinstate his or her professional license or registration without examination or penalty if their license expired while the licensee or registrant was on active duty.

Colorado and Kentucky have already enacted laws to provide comparable license fee and continuing education waivers for active duty military. Similar proposals are pending in the Michigan and Louisiana state legislatures.

THE ISSUE

Active duty military members who have professional licenses are not able to perform the duties for which they are licensed while on active military duty.

In most cases, if they do not pay to renew their license annually throughout their service period, the license will fall into delinquency and possible suspension. While the costs of individual licenses vary, they are typically hundreds of dollars.

THE SOLUTION

AB 1588 ensures military professionals will not be penalized for their military service by allowing their professional licenses to fall into delinquency and possible suspension during their service period.

It is important to find ways to support our military reservists' civilian lives while they serve our nation.

Military professionals should not be expected to pay to renew an expensive license or fulfill continuing education requirements for a professional license they cannot use on active duty.

SUPPORT

American Federation of State, County and Municipal Employees
American Legion, Department of California
American Nurses Association California
AMVETS, Department of California
Blood Centers of CA
California Association of County Veterans Service Officers
California State Commanders Veterans Council
Department of Defense State Liaison Office
Hearing Health Care Providers of California
Los Angeles County Democratic Party
Veterans of Foreign Wars, Department of California
Vietnam Veterans, Department of California

FOR MORE INFORMATION

Cody Naylor, Office of Asm. Toni Atkins
916 319 2076 | cody.naylor@asm.ca.gov

BILL NUMBER: AB 1896 AMENDED
BILL TEXT

AMENDED IN ASSEMBLY MARCH 27, 2012

INTRODUCED BY Assembly Member Chesbro

FEBRUARY 22, 2012

An act to amend the heading of Article 10 (commencing with Section 710) of Chapter 1 of Division 2 of, and to add Section 719 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 1896, as amended, Chesbro. Tribal health programs: health care practitioners.

Under existing federal law, licensed health professionals employed by a tribal health program are required to be exempt, if licensed in any state, from the licensing requirements of the state in which the tribal health program performs specified services. A tribal health program is defined as an Indian tribe or tribal organization that operates any health program, service, function, activity, or facility funded, in whole or part, by the Indian Health Service.

Existing law provides for the licensure and regulation of health care practitioners by various healing arts boards *within the Department of Consumer Affairs* .

This bill would codify that federal requirement by specifying that a *person who is licensed as a* health care practitioner *in any other state and is* employed by a tribal health program is exempt from any state licensing requirement *with respect to acts authorized under the person's license* where the tribal health program performs specified services.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The heading of Article 10 (commencing with Section 710) of Chapter 1 of Division 2 of the Business and Professions Code is amended to read:

ARTICLE 10. Federal Personnel and Tribal Health Programs

SEC. 2. Section 719 is added to the Business and Professions Code, to read:

719.

(a) A person who is licensed as a health care practitioner in any other state and is employed by a tribal health program, as defined in Section 1603 of Title 25 of the United States Code, shall be exempt from any licensing requirement described in this division with respect to acts authorized under the person's license where the tribal health program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act (25 U.S.C. Sec. 450 et seq.).

(b) For purposes of this section, "health care practitioner" means any person who engages in acts that are the subject of licensure or regulation under the law of any other state.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER:	**AB 1896**	**VERSION:**	**Amended March 27, 2012**
AUTHOR:	**Chesbro**	**SPONSORS:**	
SUBJECT:	**Healing Arts: Tribal Health Programs: Healthcare Practitioners**		

Affected Sections: Amends the heading of Article 10, and Amends Section 719 of the Business and Professions Code

Current Status: 4/18/12 – On ASM Third Reading File

Recent Updates:

Recently, it was brought to staff's attention that under the Federal provisions of the Indian Health Care Improvement Act, non-Indian patients may be extended health care at all tribal facilities. According to the California Rural Indian Health Board, Tribal Health Programs (THPs) have the authority *and desire* to serve the non-Indian population. The CRIHB notes that other non-California licensed providers also serve California residents (University of California, Veterans Administration). The CRIHB states that in many rural parts of California, THPs are the only providers in these regions and they operate as part of an integrated rural health care delivery system. They state the purpose of AB 1896 is to assist in remedying the shortage of doctors, dentists, nurses, and other providers by conforming State law to Federal law.

The board did not take a position on AB 1896 at the May 1, 2012, Board Meeting, but the committee may wish to discuss whether or not the board should take a position in light of the information provided to staff.

EXISTING LAW:

1. Provides for the licensure and regulation of a variety of healing arts professionals under various boards within the Department of Consumer Affairs, including the Board of Pharmacy.
2. Allows a hospital to enter into an agreement with the Armed Forces of U.S. to authorize a physician and surgeon, physician assistant, or registered nurse to provide medical care in the hospital under specified conditions, including that the practitioner holds a valid license in good standing to provide medical care in the D.C. or any state or territory of

the U.S., and that the practitioner registers with the appropriate California licensing board, as specified.

3. Under current federal law, a heath care professional, as defined, is able to practice his or her profession in any state or territory without licensure by that state if he or she has a current license to practice the profession and is performing authorized duties for the Department of Defense.
4. Under current federal law, the Patient Protection and Affordable Care Act (PPACA), licensed health professionals employed by a tribal health program shall be exempt, if licensed in any state, from the licensing requirement of the state in which the tribal health program performs the services described in the contract or compact of the tribal health program under the ISDEAA.

THIS BILL:

1. Seeks to codify existing federal law into state law to specify that a health care professional employed by tribal health program is exempt from state licensure if that health care professional holds a license from another state.
2. Would defines "health care practitioner" to mean any person who engages in acts that are the subject of licensure or regulation under the law of any other state.

AUTHOR'S INTENT:

According to the author, the bill is important to help address a longstanding and increasingly severe shortage of physicians in Tribal Health Clinics that exists in underserved, rural areas. The goal is to increase the number of doctors practicing in rural areas resulting in increased health care access for communities served by Tribal Health Clinics.

To address the problem of staff shortages in Tribal Health Clinics, the U.S. Congress adopted language in the Federal Affordable Care Act. This act would allow health care providers employed by Tribal Health Programs to work in States without licensure as long as they hold a license from another State. AB 1896 will align the Federal Affordable Care Act provisions with California State statute and codifying Federal Law.

BILL NUMBER: AB 1904 AMENDED
BILL TEXT

AMENDED IN SENATE JUNE 12, 2012

INTRODUCED BY Assembly Members Block, Butler, and Cook

FEBRUARY 22, 2012

An act to add Section 115.5 to the Business and Professions Code, relating to professions and vocations ~~, and making an appropriation therefor~~ .

LEGISLATIVE COUNSEL'S DIGEST

AB 1904, as amended, Block. Professions and vocations: military spouses: ~~temporary licenses.~~ *expedited licensure.*

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law provides for the issuance of reciprocal licenses in certain fields where the applicant, among other requirements, has a license to practice within that field in another jurisdiction, as specified. ~~Under existing law, licensing fees imposed by certain boards within the department are deposited in funds that are continuously appropriated.~~ *Existing law authorizes a licensee to reinstate an expired license without examination or penalty if, among other requirements, the license expired while the licensee was on active duty as a member of the California National Guard or the United States Armed Forces.*

This bill would ~~authorize~~ *require* a board within the department to ~~issue a temporary license to~~ *expedite the licensure process for* an applicant who ~~, among other requirements,~~ holds ~~an equivalent~~ *a* license *in the same profession or vocation* in another jurisdiction ~~, as specified,~~ and is married to, or in a legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders. ~~The bill would require a board to expedite the process for issuing these temporary licenses. The bill would require the applicant to pay any fees required by the board and would require that those fees be deposited in the fund used by the board to administer its licensing program. To the extent that the bill would increase the amount of money deposited into a continuously appropriated fund, the bill would make an appropriation.~~

Vote: majority. Appropriation: ~~yes~~ *no* . Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 115.5 is added to the Business and Professions Code, to read:

115.5.

(a) A board within the department shall expedite the licensure process for an applicant who meets both of the following requirements:

(1) Supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.

(2) Holds a current license in another state, district, or territory of the United States in the profession or vocation for which he or she seeks a license from the board.

(b) A board may adopt regulations necessary to administer this section.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1904 **VERSION: Amended June 12, 2012**

AUTHOR: Block, Butler and Cook

SUBJECT: Military Spouses: Expedited Licensure

BOARD POSITION: Support (Ver. 2/22/12)

Affected Sections: Add Section 115.5 to the Business and Professions Code

CURRENT STATUS: July 2, 2012 – Hearing in Senate Business, Professions and Economic Development

EXISTING LAW:

1. Allows for the regulation of various business and professions within the Department of Consumer Affairs
2. Defines the licensing requirements for the board to issue a license.

THIS BILL, AS AMENDED, WOULD:

1. Require the board to expedite the licensure process for an applicant that is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces who is assigned to a duty station in California under active duty military orders, so long as the applicant holds a current license in another state for the profession for which he or she is seeking licensure.
2. Authorize the board to adopt regulations to administer the section.

The prior version of the bill would have authorize the board to issue a "temporary license" to an applicant, as specified, to the spouse or domestic partner of an active duty member of the Armed Forces. At the May 2012 Board Meeting, the board established a "Support" position on this measure.

AUTHOR'S INTENT:

The author's office states, "State licensing and certification requirements are intended to ensure that practitioners meet a minimum level of competency. Because each state has it own licensing requirements, threes requirements often vary greatly across state lines. Consequently, the lack of license portability…can impose significant administrative and financial burdens on licensed professionals when they move across state lines."

FISCAL IMPACT:
It is anticipated that any fiscal impact associated with this version of the bill would be absorbed within the board's existing resources.

COMMENTS:
Board staff anticipates that the two primary license types would be impacted - - pharmacist and pharmacy technician.

RELATED LEGISLATION:
AB 1588 (Atkins)would provide for a waiver of licensing renewal and continuing education requirements for a reservist called to active duty.

STAFF RECOMMENDATION:
Maintain "Support" for the current version of the bill.

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 25, 2012

The Honorable Marty Block
Member, California State Assembly
State Capitol, Room 3091
Sacramento, CA 95814

RE: Assembly Bill 1904 - Support

Dear Assembly Member Block:

I am pleased to advise you that on May 1, 2012, the Board of Pharmacy met and took a ***Support*** position on your measure, AB 1904, which would allow the board to issue a temporary license to an applicant that meets the criteria for licensure and is married to, or in a legal union with, an active duty member of the Armed Forces of the United States, as specified, and would require that such an application be expedited for the issuance of the temporary license.

The board also wishes to convey its thoughts on challenges that may be faced in implementing this measure.

First, the Board of Pharmacy does not currently possess the authority to issue a "temporary" license. Though the issuance of such a license is described in AB 1904, the measure does not explicitly grant the board this authority. Also, in paragraph (4) of subdivision (a), it may be difficult to determine what acts may meet the requirements for licensure if they are tied to the term "at the time the act was committed." Depending on the act committed, this could take considerable resources and additional time to make such a determination. Finally, unless specified in statute, the board may need to promulgate regulations to specify what happens to the "temporary" license after the time it is valid. In lieu of regulations, AB 1904 could – for example – be amended to specify that a board, following the 180 days in which a temporary license is valid, may issue a regular license and cancel the temporary license.

The board proudly supports the men and women of the Armed Forces of the United States and would want to implement the provisions of the measure in the most effective and efficient manner. To that end, the board is pleased to support AB 1904.

If you have any questions, please do not hesitate to contact me at (916) 574-7911.

Sincerely,

Virginia Herold

VIRGINIA HEROLD
Executive Officer

cc: Department of Consumer Affairs

BILL NUMBER: AB 2570 INTRODUCED
BILL TEXT

INTRODUCED BY Assembly Member Hill
(Coauthor: Senator Correa)

FEBRUARY 24, 2012

An act to add Section 143.5 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 2570, as introduced, Hill. Licensees: settlement agreements.

Existing law provides that it is a cause for suspension, disbarment, or other discipline for an attorney to agree or seek agreement that the professional misconduct or the terms of a settlement of a claim for professional misconduct are not to be reported to the disciplinary agency, or to agree or seek agreement that the plaintiff shall withdraw a disciplinary complaint or not cooperate with an investigation or prosecution conducted by the disciplinary agency.

This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards, bureaus, or programs, or an entity or person acting as an authorized agent of a licensee, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board, bureau, or program. The bill would also prohibit a board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil action to pay additional moneys to the benefit of any plaintiff in the civil action.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 143.5 is added to the Business and Professions Code, to read:

143.5.

(a) No licensee who is regulated by a board, bureau, or program within the Department of Consumer Affairs, nor an entity or person acting as an authorized agent of a licensee, shall include or permit to be included a provision in an agreement to settle a civil dispute, whether the agreement is made before or after the commencement of a civil action, that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A provision of that nature is void as against public policy, and any licensee who includes or permits to be included a provision of that nature in a settlement agreement is subject to disciplinary action by the board, bureau, or program.

(b) Any board, bureau, or program within the Department of Consumer Affairs that takes disciplinary action against a licensee or licensees based on a complaint or report that has also been the subject of a civil action and that has been settled for monetary damages providing for full and final satisfaction of the parties may not require its licensee or licensees to pay any additional sums to the benefit of any plaintiff in the civil action.

(c) As used in this section, "board" shall have the same meaning as defined in Section 22, and "licensee" means a person who has been granted a license, as that term is defined in Section 23.7.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: **AB 2570** **VERSION:** **Introduced February 24, 2012**

AUTHOR: **Hill**

SUBJECT: **Licensees: Settlement Agreements**

BOARD POSITION: **Oppose Unless Amended**

Affected Sections: Add Section 143.5 to the Business and Professions Code relating to professions and vocations

Current Status: In the Senate Committee on Judiciary
As of 6/20/12, no hearing set

EXISTING LAW:

1. Provides for the licensure and regulation of a variety of healing arts professionals under various boards within the Department of Consumer Affairs, including the Board of Pharmacy.
2. Provides for the licensing, oversight and regulation of the practice of pharmacy by the Board of Pharmacy (Business and Professions Code Section 4000 et seq.)
    a. Authorizes the board to suspend or revoke a license if the holder has been convicted of certain crimes or has engaged in unprofessional conduct.

THIS BILL:

1. Would prohibit a licensee from including in a settlement to a civil suit a provision that would prohibit the other party in the dispute from contacting, filing a complaint with, or cooperating with the board or require the other party to withdraw a complaint from the board.
2. Prohibit the board from including in a disciplinary action a requirement that the licensee pay additional sums, if the civil action has been settled for monetary damages.

COMMENTS:
In 2011, the board approved language for a proposed rulemaking to add Title 16 Section 1762 to specify actions that would constitute "unprofessional conduct." Item 1 (above) is consistent with the board's regulatory proposal.

The provision that would prohibit the board from including in a disciplinary action a requirement that the licensee pay additional sums, if the civil action has been settled for monetary damages, could limit the board's discretion in its disciplinary actions.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 25, 2012

The Honorable Gerald Hill
Member, California State Assembly
State Capitol, Room 3160
Sacramento, CA 95814

RE: Assembly Bill 2570 – Oppose Unless Amended

Dear Assembly Member Hill:

I regret to advise you that the Board of Pharmacy has taken an Oppose Unless Amended position on your Assembly Bill 2570. This position was taken at the board's May 1 board meeting.

Assembly Bill 2570 would accomplish two objectives. First, the measure would prohibit a licensee, as specified, from including or permitting to be included in an agreement to settle a civil dispute, a provision that would prohibit the other party from filing a complaint with, or cooperating with the board (i.e., gag clause), or from requiring the other party to withdraw a complaint from the board – and that such a provision would subject the licensee to disciplinary action. The board supports this provision.

Subdivision (b), however, would prohibit the Board from requiring a licensee to pay restitution if a civil settlement included a monetary settlement. Such a prohibition could interfere with the board's discretion to order restitution, and it is unclear how far such a prohibition would extend. The board opposes this provision.

Thank you for the opportunity to provide comments on AB 2570. We will be happy to meet with you and your staff to discuss the board's concerns and work on resolutions. To that end, if you have any questions, please do not hesitate to contact me at (916) 574-7911.

Sincerely,

VIRGINIA HEROLD
Executive Officer

cc: Department of Consumer Affairs

BILL NUMBER: SB 1095 INTRODUCED
BILL TEXT

INTRODUCED BY Senator Rubio

FEBRUARY 16, 2012

An act to amend Sections 4190 and 4195 of, and to amend the heading of Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1095, as introduced, Rubio. Pharmacy: clinics.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy and makes a knowing violation of its provisions a crime. Existing law authorizes a surgical clinic, as defined, that is licensed by the board to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the surgical clinic. Existing law prohibits a surgical clinic from operating without a license issued by the board. Existing law requires these surgical clinics to comply with various regulatory requirements and to maintain specified records. Existing law authorizes the board to inspect a surgical clinic at any time in order to determine whether a surgical clinic is operating in compliance with certain requirements.

This bill would expand these provisions to additionally authorize an outpatient setting or an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing, subject to the requirements applicable to surgical clinics. The bill would delete the requirement that a surgical clinic be licensed by the board but would require the clinics described above to be licensed in order to receive the benefits of these provisions. The bill would specify that the board is authorized to inspect only a clinic that is licensed by the board.

Because a knowing violation of these requirements by outpatient settings and ambulatory surgical centers would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1.

This act shall be known and may be cited as the California Outpatient Pharmacy Patient Safety and Improvement Act.

SEC. 2. The heading of Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:

ARTICLE 14. Clinics

SEC. 3. Section 4190 of the Business and Professions Code is amended to read:

4190.

(a) ~~Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code~~ *For the purposes of this article, "clinic" means a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory*

surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

(b) Notwithstanding any provision of this chapter, a clinic

may purchase drugs at wholesale for administration or dispensing, under the direction of a physician *and surgeon*, to patients registered for care at the clinic, as provided in subdivision ~~(b)~~*(c)*. The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

~~(b)~~ *(c)* The drug distribution service of a ~~surgical~~ clinic shall be limited to the use of drugs for administration to the patients of the ~~surgical~~ clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

~~(c) No surgical clinic shall operate without a license issued by the board nor shall it~~ *(d) No clinic shall* be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic *licensed by the board* shall notify the board of any change in the clinic's address on a form furnished by the board.

~~(d) Any~~ *(e) If a clinic is licensed by the board, any* proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

(f) Nothing in this section shall limit the ability of a physician and surgeon or a group medical practice to prescribe, dispense, administer, or furnish drugs at a clinic as provided in Sections 2241.5, 2242, and 4170.

SEC. 4. Section 4195 of the Business and Professions Code is amended to read:
4195.

The board shall have the authority to inspect a clinic *that is licensed pursuant to this article* at any time in order to determine whether ~~a~~ *the* clinic is, or is not, operating in compliance with this article and all other provisions of the law.

SEC. 5.

No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER:	**SB 1095**	**VERSION:**	**Introduced Feb. 16, 2012**
AUTHOR:	**Rubio**	**SPONSOR:**	**Ca. Ambulatory Surgery Assn.**
SUBJECT:	**Licensing: Clinics**		

BOARD POSITION: Oppose Unless Amended (Version 2/16/12)

Affected Sections: Amend Sections 4190 and 4195 of the Business and Professions Code

CURRENT STATUS: June 26, 2012 – Set for Hearing

RECENT UPDATES:
The board established a position of Oppose Unless Amended at the May 2012 Board Meeting. A copy of the board's position letter is attached. Since that time, staff has been working with the author's office and the sponsors to resolve the board's concerns.
Amendments are expected which would allow a surgical clinic to seek board licensure, to allow a licensed surgical clinic to purchase drugs at wholesale and have a comingled drug supply.

Though not in print upon publication of this analysis, should the amended version reflect areas of agreement between the board and the author's office, staff would recommend that the board remove its opposition. Staff will provide the committee with additional information at the June 25th meeting.

EXISTING LAW:
1. Defines a surgical clinic as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. Provides that no surgical clinic licensed pursuant to Section 1204 of the Health and Safety Code may purchase drugs at wholesale or maintain a commingled drug stock unless licensed by the California State Board of Pharmacy.
2. Defines the licensing requirements for the board to issue a clinic license to surgical clinic.

THIS BILL WOULD:
1. Change the heading of Article 14 from "Surgical Clinic" to "Clinic"
2. Expand the definition of a "clinic" in Section 4190 to include:
   - Licensure by the Department of Public Health (DPH) under H&SC Section § 1204
   - An outpatient setting accredited by an approved agency as defined in H&SC § 1248

(Note: The MBC has four accreditation agencies: AAAHC, JCAHO, AAAAASF, and CMA IMQ)
- An ambulatory surgical center certified by CDPH to participate in the Medicare Program

3. Authorize any of the clinics referenced above to purchase drugs at wholesale as specified.
4. Make licensure with the board optional.
5. Require notification to the board of any changes in ownership for any clinic licensed by the board.
6. Specify that nothing in the section will limit the ability of a physician and surgeon or a group medical practice to prescribe, dispense, administer or furnish drugs at a clinic.
7. Specify that the board has authority to inspect any clinic that is licensed by the board.

AUTHOR'S INTENT:

According to the author's office, SB 1095 would expand the term "clinic" to include accredited or Medicare certified Ambulatory Surgical Centers (ASCs) and would allow these ASCs to obtain a license from the board so that they can purchase drugs at wholesale. This measure is intended to provide a solution for clinics seeking board licensure following *Capen v. Shewry* which prohibited CDPH from issuing licenses to surgical clinics that were either partially or fully owned by a physician(s). Also according to the author, approximately 90 percent of ASCs have some form of physician ownership.

FISCAL IMPACT:

The initial application fee for a clinic license is $400; annual renewal is $250. Any increase in staff processing of applications would be offset by the application/renewal fees.

Under the provisions of the bill, some accredited surgical clinics – that are not licensed by Public Health – could seek board licensure, making the Board the only regulator of the clinic's comingled drug stock. The board would require one additional Board Inspector to inspect new applicant/facilities and to conduct annual inspections of those clinics to ensure the compliance with Pharmacy laws and regulations. Personnel costs for one Board Inspector would be $164,000 per fiscal year, which would be offset by initial licensure and renewal fees.

Capen v. Shewry (2007) 155 Cal.App.4th 378, 384-385

In response to a lawsuit that the California Department of Public Health was involved in regarding the regulation of a physician-owned ambulatory surgical clinic, several legislative remedies have been offered. Past remedies have generally expanded the conditions for licensure to allow the board to license surgical clinics that participate in the Medicare Program as well as those that were accredited by an approved agency. A summary of the lawsuit is provided below.

The California Court of Appeal interpreted the Health and Safety Code exclusion highlighted above to "…exclude physician owned and operated surgical clinics from licensing by the Department, leaving them, when using general anesthesia, to accreditation and regulation by the Medical Board." (*Capen v. Shewry* (2007) 155 Cal.App.4th 378, 384-385.) In short, this ruling means that ambulatory surgical clinics owned and operated by physicians do not qualify as "surgical clinics" within the meaning of Health and Safety Code section 1204(b)(1).

Consequently, pursuant to the "*Capen* decision," the California Department of Public Health (CDPH) no longer issues their licenses to physician-owned (either in whole or in part) ambulatory surgical clinics. Although the Court opined that the Medical Board was the appropriate regulator of these physician-owned clinics, the Medical Board does not have statutory authority to regulate these facilities, only the physicians practicing in them. The Medical Board only has authority to approve the agencies that accredit outpatient surgery centers where general anesthesia will be used. (Business and Professions Code section 2216; Health and Safety Code section 1248.1.)

As a result of the ruling, the California State Board of Pharmacy could no longer issue permits to ambulatory surgical clinics (ASCs) with physician ownership.

PREVIOUS LEGISLATION

AB 847 (Lowenthal) was significantly similar to SB 1095. The board had an Oppose Unless Amended position, stating that board licensure should be required. The measure died in ASM Committee on Health without being heard.

AB 2292 (Lowenthal) of 2010 contained provisions that would have expanded the conditions under which the board can issue a clinic license including surgical clinics licensed by the Department of Public Health, those certified to participate in the Medicare Program and those accredited by an approved agency. The board had a support position on this bill that was subsequently vetoed by Governor Schwarzenegger with the following veto message.

"This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California."

AB 1574 (Plescia) of 2008 would have expended the board's licensing authority to issue a (surgical) clinic permit to clinics that are Medicate certified or accredited by a recognized accreditation agency, require the board to perform inspections within 120 days of issuing a

clinic license (and at least annually thereafter), and establish a self-assessment requirement. AB 1574 was vetoed by the Governor who stated that the bill failed to address the larger issue concerning the Capen v. Shewry ruling. The board had a Support position on this bill.

AB 2122 (Plescia) of 2008 would have required surgical clinics to meet prescribed licensing requirements and standards, including compliance with Medicare conditions of participation, and also contained provisions nearly identical to those proposed in AB 1574. AB 2122 died in Assembly Appropriations Committee. The board did not have a position on this bill.

AB 543 (Plescia) of 2007 also would have required surgical clinics to meet specified operating and staffing standards, to limit surgical procedures, as specified, and to develop and implement policies and procedures consistent with Medicare conditions of participation, including interpretive guidelines. AB 543 was vetoed by the Governor who stated that the bill did not establish appropriate time limits for performing surgery under general anesthesia, inappropriately restricted administrative flexibility, and created fiscal pressure during ongoing budget challenges. The board had a Support position on this bill.

AB 2308 (Plescia) of 2006 – This bill was vetoed by the governor. The veto message stated. "While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in these facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner." The board had no position on this bill.

COMMENTS:

Following *Capen*, the board has consistently supported measures that allowed the board to expand its licensing of clinics to also include accredited outpatient settings (as specified), or to those that are Medicare certified.

Board licensure allows a clinic to purchase drugs at wholesale and allows for a common drug supply from which prescribers may dispense in amounts to meet the patient's needs for a 72 hour period. Equally important is the regulatory oversight to ensure that a clinic complies with applicable laws and regulations related to drug distribution, to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. This includes the requirement that a clinic have a professional director and the requirement to retain a consulting pharmacist who is responsible for approving the policies and procedures in conjunction with the director.

SEC.3 (starting on p. 2. line 12)
This bill would allow expand the definition of a "clinic" to include all of the following:

- A surgical clinic licensed per H&SC 1204 (b)(1) *[these are licensed by CDPH/current law]*
- An outpatient setting accredited by an accreditation agency, as defined at H&SC 1248 [this includes in vitro fertilization clinics]
- An ambulatory surgical center that is Medicare certified

SB 1095 makes this licensure permissive – not mandatory. This would be the case even for surgical clinics that are currently licensed by the board. For those entities that are not required by to be licensed by the Department of Public Health – and for those or others who would not seek licensure from the board – there may be a lack of regulatory oversight of a clinic's drug stock to ensure it is consistent with the promotion and protection of the health and safety of the public.

SEC.3 (starting at p. 3, line 15)
SB 1095 would amend existing subdivision (c) of Section 4190 to strike the requirement that a surgical clinic be licensed by the board. The board has consistently supported measures that allow the board to expand its authority to license clinics. The board, however, has also opposed provisions that make board licensure optional (AB 847).

SEC.3 (p. 3, line 29)
SB 1095 seeks to amend Section 4190 to add a subdivision (f) which would re-state the right of a physician and surgeon to dispense drugs as provided in B&PC Section 4170. Board staff feels this amendment is unnecessary. B&PC 4170 stands as current law. To say "*Nothing in this section shall limit*…" could cause concern that drug distribution in a clinic may not be limited to an amount needed to meet the patient's needs for a 72-hour period.

SEC.4 (starting on p. 3, line 35)
SB 1095 would amend Section 4195 to specify that the board shall have the authority to inspect *only those clinics* that are licensed by the board. Should the board feel that board licensure for these clinics be mandatory, these amendments would not be necessary.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 25, 2012

The Honorable Michael J. Rubio
Member, California State Senate
State Capitol, Room 2066
Sacramento, CA 95814

RE: SB 1095 – Oppose Unless Amended

Dear Senator Rubio:

I regret to advise you that the Board of Pharmacy has taken an Oppose Unless Amended position on your Senate Bill 1095, which seeks to amend Pharmacy Law related to the licensure of surgical clinics. This position was taken at the Board Meeting held on May 1, 2012.

Attached are the proposed amendments we respectfully offer that, if incorporated, would remove the Board's opposition. The Board's amendments would ensure adequate regulatory oversight of comingled drug stocks at these clinics, and would authorize the board to inspect a clinic to determine compliance with applicable laws, whether or not the clinic is licensed by the board.

Thank you for this opportunity to provide comments on SB 1095. We will be happy to meet with you to clarify our proposed amendments and work on resolutions. Additionally, please do not hesitate to contact me (574-7911) if you have questions.

Sincerely,

VIRGINIA HEROLD
Executive Officer

Enclosure

cc: Department of Consumer Affairs

SECTION 1.
This act shall be known and may be cited as the California Outpatient Pharmacy Patient Safety and Improvement Act.
SEC. 2. The heading of Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:
ARTICLE 14. CLINICS
SEC. 3. Section 4190 of the Business and Professions Code is amended to read:
4190.
(a) For the purposes of this article, "clinic" means a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).
~~(a)~~
~~*(b) Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code clinic may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as provided in subdivision (b) (c).*~~
(b) Only a clinic licensed by the board may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as provided in subdivision (c). A separate license shall be required for each clinic location. A clinic licensed by the board shall notify the board of any change in the clinic's address on a form furnished by the board. The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.
~~(b)~~
(c) The drug distribution service of a ~~surgical~~ clinic shall be limited to the use of drugs for administration to the patients of the ~~surgical~~ clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.
~~(c)~~
~~*(d) No surgical clinic shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic licensed by the board shall notify the board of any change in the clinic's address on a form furnished by the board.*~~

Suggested amendments are shown in double underscore or double strikeout

~~(d)Any~~

~~(e)~~

(d) If a clinic is licensed by the board, any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

~~(f) Nothing in this section shall limit the ability of a physician and surgeon or a group medical practice to prescribe, dispense, administer, or furnish drugs at a clinic as provided in Sections 2241.5, 2242, and 4170.~~

SEC. 4. Section 4195 of the Business and Professions Code is amended to read:

4195.

~~The board shall have the authority to inspect a clinic that is licensed pursuant to this article at any time in order to determine whether a the clinic is, or is not, operating in compliance with this article and all other provisions of the law.~~

The board shall have the authority to inspect any clinic, whether or not licensed by the board, at any time, in order to determine:

(a) Whether a clinic licensed by the board is operating in compliance with this article and all other provisions of the law; or

(b) Whether a clinic not licensed by the board is operating in a manner that would require its licensure.

SEC. 5.

No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

BILL NUMBER: SB 1481 AMENDED
BILL TEXT

AMENDED IN ASSEMBLY JUNE 13, 2012
AMENDED IN ASSEMBLY JUNE 6, 2012

INTRODUCED BY Senator Negrete McLeod

FEBRUARY 24, 2012

An act to amend Sections 1241 and 4052.4 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 1481, as amended, Negrete McLeod. Clinical laboratories: community pharmacies.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health, subject to certain exceptions. Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to perform skin puncture in the course of performing clinical laboratory tests classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA).

This bill would exempt a community pharmacy that solely provides certain tests classified as waived under CLIA from the clinical laboratory regulations *and approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit* , provided that the tests are performed by a pharmacist, as specified, the pharmacy obtains a CLIA certificate of waiver and complies with all other requirements under CLIA, and the pharmacy notifies the public health officer of the county in which the pharmacy is located that the pharmacy is performing those tests.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1241 of the Business and Professions Code is amended to read:

1241.

(a) This chapter applies to all clinical laboratories in California or receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination, and to all persons performing clinical laboratory tests or examinations or engaging in clinical laboratory practice in California or on biological specimens originating in California, except as provided in subdivision (b).

(b) This chapter shall not apply to any of the following clinical laboratories, or to persons performing clinical laboratory tests or examinations in any of the following clinical laboratories:

(1) Those owned and operated by the United States of America, or any department, agency, or official thereof acting in his or her official capacity to the extent that the Secretary of the federal Department of Health and Human Services has modified the application of CLIA requirements to those laboratories.

(2) Public health laboratories, as defined in Section 1206.

(3) Those that perform clinical laboratory tests or examinations for forensic purposes only.

(4) Those that perform clinical laboratory tests or examinations for research and teaching purposes only and do not report or use patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or for the assessment of the health of, an individual.

(5) Those that perform clinical laboratory tests or examinations certified by the National Institutes on Drug Abuse only for those certified tests or examinations. However, all other clinical laboratory tests or examinations conducted by the laboratory are subject to this chapter.

(6) Those that register with the State Department of ~~Health Services~~ *Public Health* pursuant to subdivision (c) to perform blood glucose testing for the purposes of monitoring a minor child diagnosed with diabetes if the person performing the test has been entrusted with the care and control of the child by the child's parent or legal guardian and provided that all of the following occur:

(A) The blood glucose monitoring test is performed with a blood glucose monitoring instrument that has been approved by the federal Food and Drug Administration for sale over the counter to the public without a prescription.

(B) The person has been provided written instructions by the child's health care provider or an agent of the child's health care provider in accordance with the manufacturer's instructions on the proper use of the monitoring instrument and the handling of any lancets, test strips, cotton balls, or other items used during the process of conducting a blood glucose test.

(C) The person, receiving written authorization from the minor's parent or legal guardian, complies with written instructions from the child's health care provider, or an agent of the child's health care provider, regarding the performance of the test and the operation of the blood glucose monitoring instrument, including how to determine if the results are within the normal or therapeutic range for the child, and any restriction on activities or diet that may be necessary.

(D) The person complies with specific written instructions from the child's health care provider or an agent of the child's health care provider regarding the identification of symptoms of hypoglycemia or hyperglycemia, and actions to be taken when results are not within the normal or therapeutic range for the child. The instructions shall also contain the telephone number of the child's health care provider and the telephone number of the child's parent or legal guardian.

(E) The person records the results of the blood glucose tests and provides them to the child's parent or legal guardian on a daily basis.

(F) The person complies with universal precautions when performing the testing and posts a list of the universal precautions in a prominent place within the proximity where the test is conducted.

(7) Those individuals who perform clinical laboratory tests or examinations, approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, on their own bodies or on their minor children or legal wards.

(8) Those certified emergency medical technicians and licensed paramedics providing basic life support services or advanced life support services as defined in Section 1797.52 of the Health and Safety Code who perform only blood glucose tests that are classified as waived clinical laboratory tests under CLIA, if the provider of those services obtains a valid certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations.

(9) A community pharmacy that is providing only blood glucose, hemoglobin A1c, or cholesterol tests classified as waived under CLIA and approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, provided that all of the following requirements are satisfied:

(A) The pharmacy obtains a valid CLIA certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations.

(B) The tests are performed by a pharmacist, as defined in Section 4036, in the course of performing routine patient assessment procedures in compliance with Section 4052.4.

(C) The pharmacy notifies the public health officer of the county in which the pharmacy is located that the pharmacy is performing one or more of the tests identified in this paragraph.

(

c) Any place where blood glucose testing is performed pursuant to paragraph (6) of subdivision (b) shall register by notifying the State Department of ~~Health Services~~ *Public Health* in writing no later than 30 days after testing has commenced. Registrants pursuant to this subdivision shall not be required to pay any registration or renewal fees nor shall they be subject to routine inspection by the State Department of ~~Health Services~~*Public Health*.

SEC. 2. **Section 4052.4 of the Business and Professions Code is amended to read:**

4052.4.

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 *or paragraph (9) of subdivision (b) of Section 1241*. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 *or paragraph (9) of subdivision (b) of Section 1241*. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NO.:	**SB 1481**	**VERSION:**	**A – June 13, 2012**
AUTHOR:	**Negrete McLeod**		
SUBJECT:	**Clinical Laboratories: Community Pharmacies (CLIA Waived Tests)**		
Board Position:	**Support (Ver. 2/24/12)**		

Affected Sections: Amend Sections 1241 and 4052.4 of the Business and Professions Code

CURRENT STATUS:

June 26, 2012 – Set for Hearing in Assembly Health

RECENT UPDATES:

Amendments published in June 2012 would limit a community pharmacy to provide only blood glucose, hemoglobin A1c, or cholesterol tests classified as waived under CLIA, and approved by the FDA for sale to the public without a prescription in the form of an over-the-counter test kit, as specified. The bill also requires a pharmacy that obtains a CLIA certificate of waiver, to notify the public health officer of the county in which the pharmacy is located, that the pharmacy is performing those tests.

STAFF RECOMMENDATION:

Maintain Support (for 6/13/12 version)

EXISTING LAW:

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health, Laboratory Field Services (CDPH-LFS), subject to certain exceptions. Health and Safety Code section 1246.5 specifies tests that may be conducted pursuant to that section. Those tests are approved by the FDA for sale to the public without a prescription in the form of an over-the-counter test.

The provisions of Section 1241 of the Health and Safety Code applies to all clinical laboratories in California or those receiving biological specimens originating in California for the purpose of performing a clinical laboratory test, to all persons performing clinical laboratory tests, or

engaging in clinical laboratory practice, with specified exceptions. Among those that the provisions of Section 1241 do not apply to, include emergency medical technicians and paramedics who perform blood glucose tests that are classified as waived under CLIA, so long as the provider obtains a valid certificate of waiver and complies with other requirements for the performance of waived tests under federal regulations.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies and pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to perform skin puncture in the course of performing clinical laboratory tests in a clinic, as specified. These tests include clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (see B&PC 4052.4).

The federal Centers for Medicare & Medicaid Services (CMS) grants CLIA Waivers to entities that conduct only those tests which are deemed 'waived' by CMS. These are tests which are determined to be so simple that there is little risk of error.

THIS BILL WOULD:

Exempt from the licensure and regulation of clinical laboratories a community pharmacy that provides specified tests that are classified as waived under CLIA from the clinical laboratory regulations, provided that the tests are performed by a pharmacist, as specified, and the pharmacy obtains a certificate of waiver and complies with all other requirements under CLIA. This bill would make conforming changes to Section 4052.4 of the Business and Professions Code.

AUTHOR'S INTENT:

According to the author, there is a growing need for consumers to have access to basic laboratory tests that are related to medication therapy. The New England Healthcare Institute states that "poor medication adherence is exacting a heavy toll in the form of unnecessary illness, disability and premature mortality, particularly among the burgeoning number of chronically ill patients in the U.S. Poor medication adherence in all its manifestations costs the U.S. upwards of $290 billion per year in unnecessary health care spending. There are commercially available tests that can help patients and their medical providers monitor therapy and disease. With the results of these tests, appropriate adjustments to treatment can be made in a timely manner.

"Passage of this legislation will result in easier access to safe, simple, and economic tests – especially for low income individuals – les crowding in physicians' offices, and an improved ability of pharmacists to provide meaningful feedback to their patients when providing drug consultations required by law."

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 24, 2012

The Honorable Gloria Negrete McLeod
Member, California State Senate
State Capitol, Room 4061
Sacramento, CA 95816

RE: Senate Bill 1481- Support

Dear Senator Negrete McLeod:

I am pleased to advise you that on May 1, 2012, the Board of Pharmacy took a ***Support*** position on your measure, SB 1481, which would amend Pharmacy Law to permit a pharmacist in a community pharmacy setting to assist a patient with tests which are deemed "waived" by the federal Centers for Medicare & Medicaid Services. The practice of pharmacy is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. In addition, community pharmacists are some of the most highly-skilled and accessible health care professionals available to the public.

The board applauds your efforts to provide patients with easier access to and assistance with simple, safe, and economic tests, and is pleased to support these efforts. Thank you for your work on behalf of California's patients and also in support of California's pharmacists.

If you have any questions, please do not hesitate to contact me at (916) 574-7911.

Sincerely,

VIRGINIA HEROLD
Executive Officer

cc: Department of Consumer Affairs

Agenda Item A.2

Legislation Report

d. Other

BILL NUMBER: AB 2369 AMENDED
BILL TEXT

AMENDED IN SENATE JUNE 14, 2012
AMENDED IN ASSEMBLY MAY 21, 2012

INTRODUCED BY Assembly Member Valadao

FEBRUARY 24, 2012

An act to amend Section 5024.2 of the Penal Code, relating to prisoners.

LEGISLATIVE COUNSEL'S DIGEST

AB 2369, as amended, Valadao. Prisoners: pharmacy services.

Existing law authorizes the Department of Corrections and Rehabilitation to maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that is both cost effective and efficient, *and* that may incorporate a requirement for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.

This bill would instead require the use of ~~generic~~ *less expensive* medications *as achieved by the statewide pharmaceutical program* , when *those medications are* available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process, or unless the prescriber has indicated on the face of the prescription or on any other appropriate form for electronic prescriptions "dispense as written".

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 5024.2 of the Penal Code is amended to read: *5024.2.*

(a) The Department of Corrections and Rehabilitation is authorized to maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that is both cost effective and efficient, and may incorporate the following:

(1) A statewide pharmacy administration system with direct authority and responsibility for program administration and oversight.

(2) Medically necessary pharmacy services using professionally and legally qualified pharmacists, consistent with the size and the scope of medical services provided.

(3) ~~Written~~ *Written* procedures and operational practices pertaining to the delivery of pharmaceutical services.

(4) A multidisciplinary, statewide Pharmacy and Therapeutics Committee responsible for all of the following:

(A) Developing and managing a department formulary.

(B) Standardizing the strengths and dosage forms for medications used in department facilities.

(C) Maintaining and monitoring a system for the review and evaluation of corrective actions related to errors in prescribing, dispensing, and administering medications.

(D) Conducting regular therapeutic category reviews for medications listed in the department formulary.

(E) Evaluating medication therapies and providing input to the development of disease management guidelines used in the department.

(5) ~~A requirement for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.~~

~~(6)~~

Use of an enterprise-based pharmacy operating system that provides management with information on prescription workloads, medication utilization, prescribing data, and other key pharmacy information.

(b) *The comprehensive pharmacy services program shall require the use of less expensive medications as achieved by the statewide pharmaceutical program pursuant to Chapter 12 (commencing with Section 14977) of Part 5.5 of Division 3 of Title 2 of the Government Code, when those medications are available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process, or unless the prescriber has indicated on the face of the prescription or on any other appropriate form for electronic prescriptions "dispense as written".*

(c)

The department is authorized to operate and maintain a centralized pharmacy distribution center to provide advantages of scale and efficiencies related to medication purchasing, inventory control, volume production, drug distribution, workforce utilization, and increased patient safety. It is the intent of the Legislature that the centralized pharmacy distribution center and institutional pharmacies be licensed as pharmacies by the California State Board of Pharmacy meeting all applicable regulations applying to a pharmacy.

(1) To the extent it is cost effective and efficient, the centralized pharmacy distribution center should include systems to do the following:

(A) Order and package bulk pharmaceuticals and prescription and stock orders for all department correctional facilities.

(B) Label medications as required to meet state and federal prescription requirements.

(C) Provide barcode validation matching the drug to the specific prescription or floor stock order.

(D) Sort completed orders for shipping and delivery to department facilities.

(2) Notwithstanding any other requirements, the department centralized pharmacy distribution center is authorized to do the following:

(A) Package bulk pharmaceuticals into both floor stock and patient-specific packs.

(B) Reclaim, for reissue, unused and unexpired medications.

(C) Distribute the packaged products to department facilities for use within the state corrections system.

(3) The centralized pharmacy distribution center should maintain a system of quality control checks on each process used to package, label, and distribute medications. The quality control system may include a regular process of random checks by a licensed pharmacist.

~~(c)~~ *(d)* The department may investigate and initiate potential systematic improvements in order to provide for the safe and efficient distribution and control of, and accountability for, drugs within the department's statewide pharmacy administration system, taking into account factors unique to the correctional environment.

~~(d)~~ *(e)* The department should ensure that there is a program providing for the regular inspection of all department pharmacies in the state to verify compliance with applicable law, rules, regulations, and other standards as may be appropriate to ensure the health, safety, and welfare of the department's inmate patients.

~~(e)~~ *(f)* On March 1, 2012, and each March 1 thereafter, the department shall report all of the following to the Joint Legislative Budget Committee, the Senate Committee on Appropriations, the Senate Committee on Budget and Fiscal Review, the Senate Committee on Health, the Senate Committee on Public Safety, the Assembly Committee on Appropriations, the Assembly Committee on Budget, the Assembly Committee on Health, and the Assembly Committee on Public Safety:

(1) The extent to which the Pharmacy and Therapeutics Committee has been established and achieved the objectives set forth in this section, as well as the most significant reasons for achieving or not achieving those objectives.

(2) The extent to which the department is achieving the objective of operating a fully functioning and centralized pharmacy distribution center, as set forth in this section, that distributes pharmaceuticals to every adult prison under the jurisdiction of the department, as well as the most significant reasons for achieving or not achieving that objective.

(3) The extent to which the centralized pharmacy distribution center is achieving cost savings through improved efficiency and distribution of unit dose medications.

(4) A description of planned or implemented initiatives to accomplish the next 12 months' objectives for achieving the goals set forth in this section, including a fully functioning and centralized pharmacy distribution center that distributes pharmaceuticals to every adult facility under the jurisdiction of the department.

(5) The costs for prescription pharmaceuticals for the previous fiscal year, both statewide and at each adult prison under the jurisdiction of the department, and a comparison of these costs with those of the prior fiscal year.

~~(f)~~ *(g)* The requirement for submitting a report imposed under subdivision ~~(e)~~ *(f)* is inoperative on March 1, 2016, pursuant to Section 10231.5 of the Government Code.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER:	**AB 2369**	**VERSION:**	**Introduced February 24, 2012**
AUTHOR:	**Valadao**	**SPONSOR:**	**Author**
SUBJECT:	**Prisoners: Pharmacy Services**		

Affected Sections: Amend Section 5024.2 of the Penal Code

Current Status: In Assembly Health – as of 6/20/12 No hearing set

Recent Updates:
AB 2369 does not seek to modify existing Pharmacy Law. The board considered the introduced version of the bill (2/24/12) which required that "generic" medications be specified; however, the amended version of the bill specifies that "less expensive" medications be specified. The board has not taken a position on this measure.

EXISTING LAW:

1. Requires the Department of Corrections and Rehabilitation's (CDCR) to maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that is both cost effective and efficient.
2. Permits the CDCR to incorporate a number of components into its comprehensive pharmacy services program, to include a requirement for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.
3. Pharmacy Law, Section 4073 of the Business and Professions Code, authorizes a pharmacist filling a prescription order to select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as specified, of those drugs having the same active chemical ingredient.

THIS BILL:

1. Would amend the provisions of Section 5024.2 to require that the comprehensive pharmacy services program include a requirement that "less expensive" medications be utilized.

AUTHOR'S INTENT:
The author states "as management of prison health care services transitions out of the control of the federal Receiver and back to the jurisdiction of CDCR, it is critical that fiscal responsibility is maintained while upholding quality patient care." The author further states that generic medications are an excellent way to maintain fiscal responsibility as they have the equivalent active ingredient as the brand name versions and must work under the same safety and effectiveness standards as approved by the FDA, yet the cost is significantly less.

COMMENTS:
As amended, no impact to Pharmacy Law. The board does not have a position on this measure.

STAFF RECOMMENDATION:
None.

BILL NUMBER: SB 1185 AMENDED
BILL TEXT

AMENDED IN SENATE MAY 29, 2012
AMENDED IN SENATE APRIL 9, 2012

INTRODUCED BY Senator Price

FEBRUARY 22, 2012

An act to add *and repeal* Part 12.2 (commencing with Section 15910) ~~to~~ *of* Division 3 of Title 2 of ~~, and to repeal Section 15923 of,~~ the Government Code, relating to ~~the Centralized Intelligence Partnership Act~~ *underground operations* .

LEGISLATIVE COUNSEL'S DIGEST

SB 1185, as amended, Price. Centralized Intelligence Partnership ~~Act.~~ *Act: pilot program.*

Existing law requires various state entities, including, but not limited to, the State Board of Equalization, the Franchise Tax Board, and the Department of Justice, to enforce laws relating to the taxation and legal operation of businesses throughout the state under their respective jurisdictions.

This bill would *establish, until January 1, 2018, a pilot program to* create a multiagency partnership consisting of ~~specified state entities~~ *the Employment Development Department, Franchise Tax Board, and State Board of Equalization* , to be known as the Centralized Intelligence Partnership, to collaborate in combating illegal underground operations by, among other activities, providing a central intake process and organizational structure, with an administrator and support staff, to document, review, and evaluate data and complaints. *The bill would authorize other specified state entities to participate in the pilot program in an advisory capacity.* The bill would create an advisory committee, comprised of one representative from each entity in the partnership, *and those serving in an advisory capacity, as specified,* to provide guidance on the activities and operations of the partnership. The bill would require the advisory committee to the partnership to determine the appropriate agency to house the processing center for the partnership. The bill would authorize duly authorized representatives of members of the partnership to exchange information for the purpose of investigating illegal underground operations. The bill would require the partnership, ~~starting~~ on or before July 1, 2014, to annually report to the Legislature and entities participating in the partnership on its activities. The bill would require an additional report to be filed with the Legislature by December 1, ~~2018~~ *2016* , to include the number of complaints received by the partnership and cases investigated or prosecuted, as specified.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1.

The Legislature finds and declares all of the following:

(a) According to the Employment Development Department's analysis of findings made by the Internal Revenue Service, the underground economy in California is estimated to be between sixty billion dollars ($60,000,000,000) and one hundred forty billion dollars ($140,000,000,000) each year.

(b) According to the State Board of Equalization, an estimate of eight billion dollars ($8,000,000,000) in corporate, personal, and sales and use taxes goes uncollected in California each year, with unreported and underreported economic activity responsible for the vast majority of that total.

(c) For purposes of this section, "underground economy" means the activities of individuals, businesses, or other entities that

knowingly and intentionally use practices designed to conceal illegal or fraudulent activities that negatively impact legitimate businesses, workers, and consumers, as well as deprive the state and local governments of vital resources.

(d) The underground economy hurts all Californians. Revenues to support government services are lost, workers are forced to go without basic employment protections, and legitimate businesses are confronted with unfair competition.

(e) Since the activities of many operating in the underground economy span across multiple jurisdictions, various joint agency enforcement efforts have been undertaken to combat the underground economy, including, but not limited to, the creation of the Joint Enforcement Strike Force on the Underground Economy in 1993, and the creation of the Economic and Employment Enforcement Coalition in 2005. Furthermore, various individual agency efforts have been created, including, but not limited to, the State Board of Equalization's Statewide Compliance and Outreach Program and the Contractors' State License Board's Statewide Investigative Fraud Team. Thus, investigative collaboration among state agencies is not a new concept in California. Many collaborative efforts are already under way, pursuant to which investigators periodically meet to discuss current investigations, collaborate to conduct sting operations, and develop best practices policies.

(f) Despite significant statewide efforts, California continues to lose billions of dollars in annual revenue due to the underground economy.

(g) The Legislature intends this act to enhance existing efforts to combat the underground economy by institutionalizing collaboration among state agencies through a Centralized Intelligence Partnership, a pilot program that acquires relevant data for collaborative data analysis, economic threat assessment, strategic planning, and provides a referral tracking and value-added referral disbursement process to monitor the progress and measure the success of the partnership activities. This collaborative effort to combat the underground economy will, in turn, further aid the state in its progress toward preventing human trafficking. The Legislature recognizes that the state needs to comprehensively address the underground economy and capitalize on each agency's enforcement efforts and investigative resources by creating the Centralized Intelligence Partnership. A key element of this effort is to authorize and facilitate data and intelligence sharing among the Centralized Intelligence Partnership and state agencies. It is the intent of the Legislature in enacting this act to focus on the criminal and civil prosecution of those operating in the underground economy in flagrant violation of the law. Businesses that are in compliance with state employment, safety, licensing, and tax laws that are found to have committed minor or inadvertent violations of existing law are to be addressed through other administrative procedures.

(h) It is the intent of the Legislature that this act be part of ongoing efforts by the Legislature to combat the underground economy in this state through legislation.

SEC. 2. Part 12.2 (commencing with Section 15910) is added to Division 3 of Title 2 of the Government Code, to read:

15910.

This part shall be known, and may be cited, as the Centralized Intelligence Partnership Act.

15912.

(a) The Centralized Intelligence Partnership is hereby established in state government as a pilot program.

(b) For purposes of this part, the term "partnership" shall refer to the Centralized Intelligence Partnership.

15914.

(a) The partnership shall include all of the following state entities:

(1) Employment Development Department.

(2) Franchise Tax Board.

(3) State Board of Equalization.

(b) In addition to the agencies listed in subdivision (a), the following agencies may participate in the pilot program in an advisory capacity to the partnership:

(1) California Health and Human Services Agency.

(2) Department of Consumer Affairs.

(3) Department of Industrial Relations.

(4) Department of Insurance.

(5) Department of Justice.

(6) Department of Motor Vehicles.

(c) If, in its normal course of investigation, an agency listed in subdivision (b) discovers a violation of law that would result in increased tax revenues to the state, that agency shall notify the appropriate tax agency listed in subdivision (a).

15916.

(a) The advisory committee to the Centralized Intelligence Partnership is hereby established to provide guidance to, and advice on, the activities and operations of the partnership.

(b) The advisory committee shall be comprised of one representative from each of the entities in the partnership listed under subdivision (a) of Section 15914. Each representative shall be appointed by the head of the entity in the partnership and serve at the pleasure of the appointing authority. An agency participating in

an advisory capacity may provide a representative to the advisory committee to offer guidance and advice to the partnership.

(c) The advisory committee shall meet as needed, but at least quarterly, to conduct its business.

15918.

(a) To serve the best interests of the state by combating the underground economy, the partnership shall do all of the following to combat illegal underground operations:

(1) Provide a central intake process and organizational structure to document, review, and evaluate data and complaints.

(2) Establish a processing center to receive and analyze data, share complaints, and research leads from the input of each impacted agency.

(3) Provide participating and nonparticipating agencies with value-added investigative leads where collaboration opportunities exist for felony-level criminal investigations, including, but not limited to, referring leads to agencies with appropriate enforcement jurisdiction.

(4) Provide that each participating and nonparticipating agency retain jurisdictional authority over whether to pursue partnership strategies or collaborative investigative leads based upon the direction of their respective governing structures or available resources.

(5) Document and provide intake data analysis, analytic data findings, referrals, collaborative opportunities, outcomes, emerging evasion trends, lessons learned, as well as additional enforcement, administrative, and legislative opportunities.

(b) The scope of activities and projects undertaken by the partnership shall be consistent with the amount of funds appropriated by the Legislature.

(c) The advisory committee to the partnership shall determine the appropriate agency to house the processing center for the partnership.

(d) The partnership may hire an administrator and staff.

15920.

Duly authorized representatives of members of the partnership, and agencies participating in an advisory capacity, may exchange intelligence, data, documents, information, complaints, or lead referrals for the purpose of investigating illegal underground operations. Any member or ex-member of the partnership, any agent employed by any member of the partnership, or any person who has at any time obtained such knowledge from any of the foregoing partners or persons, shall not divulge, or make known in any manner not provided by law, any of the confidential information received by, or reported to, the partnership. Information exchanged pursuant to this section shall retain its confidential status and shall remain subject to the confidentiality provisions contained in the following provisions:

(a) California Health and Human Services Agency: Subdivision (c) of Section 6254 of this code and Section 14100.2 of the Welfare and Institutions Code.

(b) Department of Consumer Affairs: Section 30 of the Business and Professions Code and Section 56.29 of the Civil Code.

(c) Department of Industrial Relations: Sections 11181, 11183, and 15553 of this code, Section 1877 of the Insurance Code, and Sections 92, 138.7, 1026, 3762, 6309, 6322, 6396, and 6412 of the Labor Code.

(d) Department of Insurance: Section 11180 of this code and Sections 1872.6, 1873, 1874.2, 1875.1, 1877.1, 1877.3, 1877.4, and 1877.5 of the Insurance Code.

(e) Department of Justice: Section 11183.

(f) Department of Motor Vehicles: Sections 1808.2, 1808.4, 1808.5, 1808.6, 1808.21, 1808.24, and 12800.5 of the Vehicle Code.

(g) Employment Development Department: Sections 1094 and 1095 of the Unemployment Insurance Code.

(h) Franchise Tax Board: Sections 19542, 19542.1, and 19542.3 of the Revenue and Taxation Code.

(i) State Board of Equalization: Section 15619 of this code, Section 42464.8 of the Public Resources Code, and Sections 7056, 7056.5, 8255, 9255, 9255.1, 30455, 38705, 38706, 43651, 45981, 45982, 45983, 45984, 46751, 50159, 50160, 50161, 55381, 60608, and 60609 of the Revenue and Taxation Code.

15922.

On or before July 1, 2014, and annually thereafter, the partnership shall report on its activities and accomplishments to the Legislature and each entity in the partnership.

15923.

The partnership shall submit to the Legislature on or before December 1, 2016, a report of the pilot program that includes, but is not limited to, the following information:

(a) The number of leads or complaints received by the partnership.

(b) The number of cases investigated or prosecuted through civil action or criminal prosecution.

(c) Recommendations for modifying, eliminating, or continuing the operation of any or all of the provisions of this part.

15924.

This part shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1185 **VERSION: As Amended April 9, 2012**

AUTHOR: Price **SPONSOR:** State Board of Equalization

SUBJECT: Centralized Intelligence Partnership Act

Board Position: None

AFFECTED SECTIONS: An act to add Part 12.2 (commencing with Section 15910) to Division 3 of Title 2 of, and to repeal Section 15923 of, the Government Code

CURRENT STATUS: July 2, 2012 – Set for Hearing in Assembly Revenue & Taxation

Recent Updates:
The board considered the April 9, 2012, version and did not take a position on the measure.

As amended, this bill would create a Centralized Intelligence Partnership ("partnership") as a pilot program – until January 1, 2018 – for the purpose of combating the underground economy. This partnership would institutionalize collaboration among state agencies, with a key element being to authorize and facilitate data and intelligence sharing among the partnership and state agencies. The partnership shall consist of the Employment Development Department, the Franchise Tax Board and the State Board of Equalization. The Department of Consumer Affairs is one of six state agencies designated that *may* participate in the pilot program in an advisory capacity. Should the DCA wish to participate, the DCA may provide a representative to the advisory committee, which shall meet at least quarterly. The bill in its current form authorizes participating agencies to exchange intelligence, data, documents, information, complaints, leads, etc. SB 1185 specifies that the partnership shall report to the Legislature, and specifies the frequency and content of those reports.

EXISTING LAW:

1. Establishes several different government entities responsible for oversight, regulation and enforcement of various businesses and individuals doing business in California including:
    a. California Health and Human Services Agency
    b. Department of Consumer Affairs
    c. Department of Industrial Relations
    d. Department of Insurance
    e. Department of Justice
    f. Department of Motor Vehicles
    g. Employment Development Department
    h. Franchise Tax Board
    i. State Board of Equalization

2. B&PC Section 110 specifies that the department (DCA) has possession and control of all records etc. held for use by all bodies, offices and officers comprised within the department.

THIS BILL WOULD:

1. Create the Centralized Intelligence Partnership as a pilot program through January 1, 2018.
2. Specify that the advisory committee is charged with combating the underground economy and specifies the general scope of the committee's process.
3. Allow for the sharing of information between the members of the advisory committee and provides that information shared via this process will retain is confidential status as authorized by law.
4. Establish reporting requirements for this advisory committee.

AUTHOR'S INTENT:

The author's fact sheet indicates that this measure "seeks to address the problems caused by California's underground economy. This legislation establishes a multiagency collaboration, which will be known as the Centralized Intelligence Partnership (CIP). The CIP will facilitate consumer complaints, perform research that will assist in the recapturing of unreported taxes, aide in exposing employers who exploit workers and assist in efforts to investigate and prosecute violations."

COMMENTS (prior version):

Recent information received from the Board of Equalization indicates that this measure is silent in several areas to allow for flexibility in the establishment of the partnership. Once established, the partnership would most likely determine the scope of investigations that would be done under its purview. It is not the intent of this legislation to require all investigations initiated by the board to be evaluated and investigated through this partnership.

The board has working relationships with several other regulatory agencies including the Department of Public Health, Department of Health Care Services as well as local, state and federal enforcement agencies. Board inspectors participate in joint investigations on a fairly routine basis.

Both the department and board staff recommends that at minimum amendments be offered to the author's office to include specific reference to two Government Code sections that relate to access to board records.

FISCAL IMPACT:

Based on discussion with BOE, it is unclear the number of additional investigations the board would be involved in investigating. BOE estimates that it will realize a 120% increase in investigations.

According to the analysis prepared for the Senate Committee on Governmental Organization, BOE estimates an revenue increases of $15M will be associated with these cooperative enforcement activities.

Agenda Item B

Regulation Report

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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN, JR.

Legislation and Regulation Committee

Shirley Wheat, Chair, Public Member
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LEGISLATION AND REGULATION COMMITTEE REPORT

PART B – REGULATION

1. Board Approved - Undergoing Review by the Administration

ATTACHMENT 1

a. Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns – To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

b. Amend Title 16 Section 1728 – Requirements for Pharmacist Examination – Amend to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

On June 18, 2012, staff was advised that the Office of Administrative Law completed its review and approved the Board's regulation. The regulation will take effect on July 18, 2012.

Attachment 1 contains a copy of the Adopted Text. The board's regulation will require a Pharmacist Intern applicant to submit with his or her application a Self-Query Report from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDBHIPDB). This regulation also will require an applicant seeking board authority to take the pharmacist licensure examination to submit with his or her application a Self-Query Report from the NPDB-HIPDB. The board determined that the requirement(s) to submit a Self-Query Report, as specified in the proposal, is necessary and pertinent to the board's investigation of an applicant and will allow the board to determine if an applicant has been the subject of discipline in another state prior to making a decision on an application. This is the same type of Self-Query Report that was recently approved in 2011 for Pharmacy Technician applicants.

2. Board Sponsored – Regulations Currently Noticed

ATTACHMENT 2

a. Proposed Amendments to Title 16, Section 1746 – Emergency Contraception Protocol Review and Discussion of Comments Submitted During 45-day Comment Period *[45-day comment period: January 6 – February 20, 2012]*

The board considered 45-day public comments at the May 1, 2012 Board Meeting and rejected the comments. The Medical Board will also have to reject the comments and – at that time – the board can move forward to complete the rulemaking.

The Medical Board will be conducting their Quarterly Board Meeting in July 2012.

Business and Professions Code Section 4052.3 authorizes a pharmacist to initiate emergency contraception therapy in accordance with either (1) standardized procedures or protocols developed by the pharmacist and an authorized prescriber, as specified; and (2) standardized procedures or protocols developed and approved by both the Medical Board of California and the Board of Pharmacy, as specified.

The current state protocol was developed by the Medical Board in 2004 and was adopted by the Board of Pharmacy that same year. Title 16 CCR § 1746 became operative on December 2, 2004. Since that time, there have been changes in the availability of emergency contraception medicine, the manufacturers who produce the medication. The protocol also has a typographical error that requires correction (mcg instead of mg).

Following the adoption of a new emergency contraception protocol, the board will then need to update its patient information fact sheet. This fact sheet is required by Section 4052.3(e) of the Business and Professions Code and is provided to the patient by the pharmacist using the protocol to dispense emergency contraception. The update of a fact sheet would be vetted through the board's Communication and Public Education Committee. A copy of the board's proposed text is provided in Attachment 2.

b. Proposed Amendments to § 1735.1, 1735.2, 1735.3 and 1752.2 Related to Compounding

On March 9, 2012, the board noticed for a 45-day public comment period, proposed amendments to Title 16 California Code of Regulations beginning at Section 1735.1 related to compounding drug products. The 45-day comment period concluded on April 23, 2012, and the board conducted a Regulation on May 1, 2012, which coincided with the May Board Meeting. At that meeting the board voted to modify the language related to the labeling of cytotoxic products, and also to proposed Section 1735.3(a) related to "redispensed CSPs" – noting that board staff shall verify the USP 797 language that is to be incorporated. To that end, the board has subscribed to USP 797 and once the language is verified, the notice of modified text will be issued for a 15-day comment period.

A copy of the 45-day Notice language is attached.

3. Board Approved – Awaiting Notice (Information Only)

a. Proposed Addition of Section 1762 – Unprofessional Conduct

In October 2010, the board began discussions to add 16 CCR § 1762 to implement components of the DCA's Consumer Protection Enforcement Initiative relative to unprofessional conduct. In February 2011 the board addressed draft language and moved to initiate the rulemaking process to amend Section 1762 to specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and authorize the board to revoke a license or deny an application for an act requiring an individual to register as a sex offender.

Staff is working to prepare a rulemaking package for a 45-day public comment period. A copy of the approved text for notice is attached, which combines proposals for Sections 1745, 1762, and 1769.

b. Proposed Addition of Section 1769 – Application Review and Criteria for Rehabilitation

Protection Enforcement Initiative with regarding to 16 CCR § 1769 – a proposal that would authorize the board to request that an applicant for licensure undergo an examination, as specified, to determine if the applicant is safe to practice. The board directed that staff initiate the rulemaking process to amend 16 CCR § 1769, specifying that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days, and that within 60 days of the evaluation, the report be received by the board.

c. Proposed Amendment of Title 16 Section 1745 – Partial Fill of Schedule II Controlled Substance

At the October 2010 Board Meeting the board voted to initiate a rulemaking to amend Section 1745(c)(2) to allow pharmacies to maintain electronic records or document on the original prescription when partially filling a Schedule II controlled substance. The language approved by the board is below. Staff is working to prepare a rulemaking package for a 45-day public comment period.

> 1745(c)(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

4. Proposed Regulations Being Discussed by Committees (Not for Action – Update Only)

a. Licensing Committee

- Updates to the USP Standards Reference Manual
- Standards for Agencies that Accredit Licensed Sterile Injectable Compounding Pharmacies
- Continuing Education
- Accreditation Agencies for Continuing Education
- Self-Assessment of a Veterinary Food-Animal Drug Retailer

b. Enforcement Committee

- Requirements for Unique ID Numbers for Rx / E-Pedigree
- Development of “Grandfathering” Provisions for Non-Pedigree Dangerous Drugs

c. Communication and Public Education Committee

- Notice to Consumers Posters / Video Display Format Option / Interpreter Availability

Order of Adoption

Board of Pharmacy

California Code of Regulations

Add Section 1727.2. to Article 3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1727.2. Requirements for Pharmacist Intern.

Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4207 and 4208, Business and Professions Code.

Amend Section 1728. in Article 3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

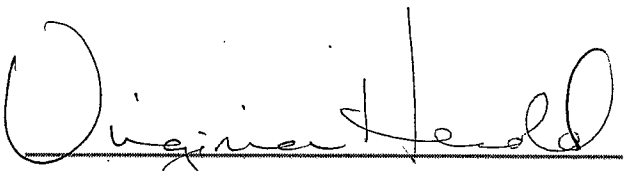
(5) A sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Note: Authority cited: Sections 851 and 4005, Business and Professions Code.

Reference: Sections 144, 851 and 4200, Business and Professions Code.



Virginia Herold
Executive Officer
Board of Pharmacy

Title 16. Board of Pharmacy
Proposed Language

To Amend § 1746 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section ~~4052(a)(8)~~ 4052.3.(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

~~(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.~~

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication ~~within required limits~~ and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and ~~state~~ communicate the following:

> Are you allergic to any medications?
>
> Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) ~~of~~ after unprotected intercourse. ~~EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.~~
>
> EC use will not interfere with an established or implanted pregnancy.
>
> If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. Other options for EC include consultation with your physician regarding insertion of an IUD.

(4) The pharmacist shall provide ~~the~~ a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a

patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section ~~4052(b)(3)~~ 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication ~~compatible with product information~~ from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in ~~the~~ this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

~~(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.~~

(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Dedicated Emergency Contraception

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynétics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	**Manufacturer**	**Tablets per Dose (two doses 12 hours apart*)**	**Ethinyl Estradiol per Dose (mg)**	**Levonorgestrel per Dose (mg)****
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in eachdoes is twice the amount of levonorgestrel

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception			
Brand	Dose	Ethinyl Estradiol per dose (mcg)	
One Dose Regimen			
Plan B™ One-Step	1 tablet	0	1.5mg levonorgestrel
ella™	1 tablet	0	30mg ulipristal
Two Dose Regimen			
Next Choice™	1 tablet per dose	0	1.5mg levonorgestrel
Oral Contraceptive Pills			
Brand	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per dose (mcg)	Levonorgestrel per dose (mg)*
Alesse	5 pink tablets	100	0.50
Aviane	5 orange tablets	100	0.50
Levlen	4 light-orange tablets	120	0.60
Levlite	5 pink tablets	100	0.50
L*evora*	4 white tablets	120	0.60
Lo/Ovral	4 white tablets	120	0.50
Low-Ogestrel	4 white tablets	120	0.60
Nordette	4 light-orange tablets	120	0.60
Ogestrel	2 white tablets	100	0.50
Ovral	2 white tablets	100	0.50
Tri-Levlen	4 yellow tablets	100	0.50
Triphasil	4 yellow tablets	120	0.50
Trivora	4 pink tablets	120	0.50
Ovrette	20 yellow tablets	0	0.75

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Anti-Nausea Treatment Options For Use With Emergency Contraception		
Drug	**Dose**	**Timing of Administration**
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ~~ECP~~ EC dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code. Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.

Board of Pharmacy
Proposed Language

To Amend Section 1735.1 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.1. Compounding Definitions.

(a) "Equipment" means items that must be calibrated, maintained or periodically certified.

~~(a)~~ (b) "Integrity" means retention of potency until the expiration date noted on the label.

~~(b)~~ (c) "Potency" means active ingredient strength within +/- 10% of the labeled amount.

~~(c)~~ (d) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

~~(d)~~ (e) "Strength" means amount of active ingredient per unit of a compounded drug product.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend Section 1735.2 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of

patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A “reasonable quantity” as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

~~(2)~~ (4) Inactive ingredients to be used.

~~(3)~~ (5) Process and/or procedure used to prepare the drug.

~~(4)~~ (6) Quality reviews required at each step in preparation of the drug.

~~(5)~~ (7) Post-compounding process or procedures required, if any.

~~(6) Expiration dating requirements.~~

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. ~~01/11~~ 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend Section 1735.3 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.3. Records of Compounded Drug Products.

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within ~~twenty-four~~ seventy-two (72) hours and stored in accordance with United States Pharmacopeia Standards to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

~~(7) The equipment used in compounding the drug product.~~

~~(8)~~ (7) A pharmacy assigned reference or lot number for the compounded drug product.

~~(9)~~ (8) The expiration date of the final compounded drug product.

~~(10)~~ (9) The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Note: Authority cited: Sections 4005, 4127 and 4169, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend Section 1751.2 of Article 7 of Division 17 of Title 16 to read as follows:

§ 1751.2. Sterile Injectable Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

(a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.

(b) Name and concentrations of ingredients contained in the sterile injectable product.

(c) Instructions for storage and handling.

(d) All cytotoxic agents shall bear a special label which states “Chemotherapy - Dispose of Properly~~.~~” or “Cytotoxic Product – Dispose of Properly.”

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Title 16. Board of Pharmacy
Proposed Language

To Amend Section 1745 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1745. Partial Filling of Schedule II Prescriptions.
(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:

(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or

(2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~**and**~~ **or** on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If

the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4301, Business and Professions Code; and Sections 11055, 11153, 11154, 11166, 11200, Health and Safety Code.

To Add Section 1762 to Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1762. Unprofessional Conduct Defined.

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later.

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

To Amend Section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1769. Criteria for Rehabilitation.

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4200 and 4400, Business and Professions Code.